AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Wednesday,
No. 183 September 21, 2016

Pages 64759–65168

OFFICE OF THE FEDERAL REGISTER

1985

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.ofr.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.fdsys.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 81 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC	
Subscriptions:	
Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**
Single copies/back copies:	
Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800** **(Toll-Free)**
FEDERAL AGENCIES	
Subscriptions:	
Assistance with Federal agency subscriptions:	
Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

Printed on recycled paper.

Contents

Federal Register
Vol. 81, No. 183
Wednesday, September 21, 2016

Agricultural Marketing Service

RULES
Domestic Dates Produced or Packed in Riverside County, CA:
  Decreased Assessment Rate, 64759–64761
PROPOSED RULES
Cherries Grown in Designated Counties in Washington:
  Increased Assessment Rate, 64785–64787

Agriculture Department

See Agricultural Marketing Service
See Forest Service
See Rural Utilities Service

Children and Families Administration

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Unaccompanied Refugee Minors Placement and Outcomes Reports, 64910–64911

Commerce Department

See Economic Development Administration
See Foreign-Trade Zones Board
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration
See Patent and Trademark Office

Commodity Futures Trading Commission

NOTICES
Charter Renewals:
  Agricultural Advisory Committee, 64878

Consumer Product Safety Commission

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 64878–64880

Defense Department

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 64884–64885
Arms Sales, 64880–64884
Charter Amendments:
  Department of Defense Federal Advisory Committees, 64880

Denali Commission

NOTICES
Fiscal Year 2017 Draft Work Plan, 64885–64887

Drug Enforcement Administration

NOTICES
Decisions and Orders:
  Charles Szyman, D.O., 64937–64940
  Kevin L. Lowe, M.D., 64949–64951
  Richard J. Settles, D.O., 64940–64949
Manufacturers of Controlled Substances; Applications:
  Nanosyn, Inc., 64949

Economic Development Administration

PROPOSED RULES
Innovative Technologies in Manufacturing Loan Guarantee Program, 64787–64805
Regional Innovation Program, 64805–64812
NOTICES
Trade Adjustment Assistance Eligibility; Petitions, 64870

Education Department

NOTICES
Authorization of Subgrants for Disability Innovation Fund; Automated Personalization Computing Project, 64887–64888
Performance Review Board Membership, 64888–64889

Energy Department

See Federal Energy Regulatory Commission

NOTICES
Authority to Import and Export Natural and Liquefied Natural Gas:
  Clean Energy, Rio Grande LNG, LLC, et al., 64889–64890
Filings:
  Self-Certification of Coal Capability under Powerplant and Industrial Fuel Use Act, 64889

Environmental Protection Agency

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 64902–64904
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  National Oil and Hazardous Substances Pollution Contingency Plan Regulation, 64894–64895
  NESHAP for Automobile and Light-Duty Truck Surface Coating, 64907
  NESHAP for Gasoline Distribution Facilities, 64907–64908
  NESHAP for Stationary Combustion Turbines, 64905
  Registration of Fuels and Fuel Additives—Health-Effects Research Requirements for Manufacturers, 64896–64897
Cross-Media Electronic Reporting:
  Authorized Program Revision Approval, State of Alaska, 64904–64905
  Authorized Program Revision Approval, State of Oregon, 64904
Data Transfers:
  Summitec Corp., Versar, Inc., and CDM/CSS-Dynamac Joint Venture; Correction, 64906–64907
Meetings:
  Great Lakes Advisory Board; Teleconference, 64905–64906
  National Environmental Justice Advisory Council, 64895–64896
Pesticide Product Registrations:
  Certain Pesticide Registrations and Amendment to Terminate a Certain Use; Cancellation, 64897–64902

Federal Aviation Administration

NOTICES

- Environmental Assessments; Availability, etc.:
  - Runway 13/31 Shift/Extension and Associated Improvements Project for Detroit Lakes-Becker County Airport, Detroit Lakes, MN, 64977–64978
- Meetings:
  - International Civil Aviation Organization Dangerous Goods Panel, 64976–64977
- Passenger Facility Charge Program, 64977
- Schedule of Charges Outside United States, 64976

Federal Communications Commission

PROPOSED RULES

- Procedures for Commission Review of State Opt-Out Requests from FirstNet Radio Access Network, 64825–64829

Federal Election Commission

NOTICES

- Special Election Filing Dates:
  - Kentucky 1st Congressional District, 64908–64909

Federal Energy Regulatory Commission

NOTICES

- Combined Filings, 64891–64894
- Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
  - Lindahl Wind Project, LLC, 64893
  - North Lancaster Ranch, LLC, 64891
  - Oliver Wind III, LLC, 64892–64893

Federal Highway Administration

NOTICES

- Environmental Impact Statements; Availability, etc.:
  - Suffolk County, NY, 64978

Federal Maritime Commission

NOTICES

- Agreements Filed, 64909

Federal Reserve System

NOTICES

- Changes in Bank Control:
  - Acquisitions of Shares of a Bank or Bank Holding Company, 64910
- Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 64909–64910
- Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Corrections, 64909

Fish and Wildlife Service

PROPOSED RULES

- Endangered and Threatened Species:
  - 90-Day Findings on 10 Petitions; Correction, 64829
- Endangered and Threatened Wildlife and Plants:
  - 12-Month Findings on Petitions to List Nine Species, 64843–64857
  - Status for Pearl Darter, 64857–64868
  - Status for Sonoyta Mud Turtle, 64829–64843

Food and Drug Administration

RULES

- Medical Devices:
  - General and Plastic Surgery Devices; Classification of Magnetic Surgical Instrument System, 64761–64763

NOTICES

- Drug Products from Sale for Reasons other than Safety or Effectiveness; Withdrawals:
  - CHLOROMYCETIN (Chloramphenicol) Capsules, 50 Milligrams and 100 Milligrams, and Three Other Products, 64914–64916
- Guidance:
  - Application of Statutory Factors in Determining When Risk Evaluation and Mitigation Strategy is Necessary, 64911–64913
  - Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices, 64913–64914
  - Modifications to List of Recognized Standards, Recognition List Number 045, 64917–64920
  - Reporting of Computational Modeling Studies in Medical Device Submissions, 64916–64917

Foreign-Trade Zones Board

NOTICES

- Proposed Production Activities:
  - Canon Virginia, Inc. Subzone 20D (Toner Cartridges) Newport News, VA, 64870
  - Givaudan Flavors Corp. (Flavor Compounds), Lakeland, FL; Foreign-Trade Zone 79, Tampa, FL, 64870–64871

Forest Service

NOTICES

- Environmental Impact Statements; Availability, etc.:
  - Revision of Land Management Plan for Rio Grande National Forest, CO, 64869

Health and Human Services Department

See Children and Families Administration

See Food and Drug Administration

See National Institutes of Health

RULES

- Clinical Trials Registration and Results Information Submission, 64982–65157

Housing and Urban Development Department

RULES

- Equal Access in Accordance with an Individual's Gender Identity in Community Planning and Development Programs, 64763–64782

NOTICES

- Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  - Disaster Recovery Grant Reporting System, 64934–64935
  - Equal Access Regardless of Sexual Orientation, Gender Identity, or Marital Status for HUD's Community Planning and Development Programs, 64930–64932
  - Small Area Fair Market Rent Demonstration Evaluation, 64929–64930
- Guidance:
  - Eligibility of Independent Students for Assisted Housing under Section 8 of U.S. Housing Act, 64932–64933

Indian Affairs Bureau

NOTICES

- Indian Gaming:
  - Approval of Tribal-State Class III Gaming Compact in State of South Dakota, 64935–64936

Industry and Security Bureau

NOTICES

- Orders Denying Export Privileges:
  - Francisco Javier Mendoza-Esquivel, Big Spring, TX, 64871–64872

Interior Department

See Fish and Wildlife Service
See Indian Affairs Bureau
See Land Management Bureau

International Trade Administration

NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
  Oil Country Tubular Goods from Republic of Korea, 64873–64874
Meetings:
  Advisory Committee on Supply Chain Competitiveness, 64872–64873

International Trade Commission

NOTICES
Investigations; Determinations, Modifications, and Rulings, etc.:
  Certain Personal Transporters and Components Thereof, 64936–64937

Justice Department

See Drug Enforcement Administration
NOTICES
Applications:
  National Commission on Forensic Science, 64951–64952

Labor Department

See Workers Compensation Programs Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Labor Standards for Federal Service Contracts, 64952

Land Management Bureau

NOTICES
Meetings:
  North Slope Science Initiative Science Technical Advisory Panel, 64936

National Highway Traffic Safety Administration

NOTICES
Petitions for Import Eligibilities:
  Nonconforming Model Year 2009 Jeep Compass Multipurpose Passenger Vehicles, 64978–64980

National Institutes of Health

NOTICES
Dissemination of NIH-Funded Clinical Trial Information, 64922–64928
Meetings:
  Center for Scientific Review, 64920–64922
  National Center for Advancing Translational Sciences, 64928–64929
  National Heart, Lung, and Blood Institute, 64921

National Oceanic and Atmospheric Administration

RULES
Fisheries of the Exclusive Economic Zone Off Alaska:
  Exchange of Flatfish in Bering Sea and Aleutian Islands Management Area, 64782–64784
  Shortraker Rockfish in Western Regulatory Area of Gulf of Alaska, 64784
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 64874–64875

Nuclear Regulatory Commission

NOTICES
Guidance:
  Nuclear Power Plant Instrumentation for Earthquakes, 64954–64955
  Shipping, Receiving, and Internal Transfer of Special Nuclear Material, 64955–64956

Patent and Trademark Office

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Deposit of Biological Materials, 64875–64877
  Legal Processes, 64877–64878
  Pro Bono Survey, 64877

Personnel Management Office

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Designation of Beneficiary, Federal Employees' Group Life Insurance, 64958–64959
  Letter Reply to Request for Information; Former Spouse Survivor Annuity Election; Information on Electing Survivor Annuity for Former Spouse, 64957–64958
  Self-Certification of Full-Time School Attendance for School Year and Information and Instructions for Completing Self-Certification of Full-Time School Attendance for School Year, 64956–64957
  We Need Important Information about Your Eligibility for Social Security Disability Benefits, 64957

Postal Regulatory Commission

NOTICES
New Postal Products, 64959

Postal Service

NOTICES
Product Changes:
  First-Class Package Service Negotiated Service Agreement, 64959–64960
  Parcel Select Negotiated Service Agreement, 64959–64960
  Priority Mail Negotiated Service Agreement, 64960

Presidential Documents

PROCLAMATIONS
Northeast Canyons and Seamounts Marine National Monument (Proc. 9496), 65159–65167

Rural Utilities Service

NOTICES
Depreciation Rates, 64869

Securities and Exchange Commission

NOTICES
Meetings; Sunshine Act, 64966
Self-Regulatory Organizations; Proposed Rule Changes:
  Bats BZX Exchange, Inc., 64960–64963
  Bats EDGX Exchange, Inc., 64963–64965
  Financial Industry Regulatory Authority, Inc., 64969–64970
  New York Stock Exchange, LLC, 64966–64969

State Department

NOTICES
Arms Sales, 64971–64976

Susquehanna River Basin Commission
PROPOSED RULES
Review and Approval of Projects, 64812–64825

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See National Highway Traffic Safety Administration

Treasury Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 64980

Workers Compensation Programs Office
NOTICES
Meetings:
  Advisory Board on Toxic Substances and Worker Health, 64953–64954

Separate Parts In This Issue

Part II
Health and Human Services Department, 64982–65157

Part III
Presidential Documents, 65159–65167

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR
Proclamations:
9496 65161

7 CFR
987 64759
Proposed Rules:
923 64785

13 CFR
Proposed Rules:
311 64787
312 64805

18 CFR
Proposed Rules:
806 64812
808 64812

21 CFR
878 64761

24 CFR
5 64763

42 CFR
11 64982

47 CFR
Proposed Rules:
90 64825

50 CFR
679 (2 documents) 64782, 64784
Proposed Rules:
17 (4 documents) 64829, 64843, 64857

Rules and Regulations

Federal Register

Vol. 81, No. 183

Wednesday, September 21, 2016

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 987

[Docket No. AMS–SC–16–0084; SC16–987–1 IR]

Domestic Dates Produced or Packed in Riverside County, California; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This rule implements a recommendation from the California Date Administrative Committee (committee) for a decrease in the assessment rate established for the 2016–17 and subsequent crop years from $0.10 to $0.05 per hundredweight of dates handled. The committee locally administers the marketing order, which regulates the handling of dates produced or packed in Riverside County, California. Assessments upon date handlers are used by the committee to fund reasonable and necessary expenses of the program. The crop year begins October 1 and ends September 30. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective September 22, 2016. Comments received by November 21, 2016, will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Terry Vawter, Senior Marketing Specialist, or Jeffrey Smutny, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Terry.Vawter@ams.usda.gov* or *Jeffrey.Smutny@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement and Order No. 987, both as amended (7 CFR part 987), regulating the handling of dates produced or packed in Riverside County, California, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, Riverside County, California, date handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable dates beginning October 1, 2016, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule decreases the assessment rate for the 2016–17 and subsequent crop years from $0.10 to $0.05 per hundredweight of dates.

The California date order provides authority for the committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the committee are date producers and handlers from Riverside County, California. They are familiar with the committee's needs and the costs of goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2015–16 crop year, the committee recommended, and USDA approved, an assessment rate that would continue in effect from crop year to crop year unless modified, suspended, or terminated by USDA upon recommendation and information supplied by the committee or other information available to USDA.

The committee met on June 22, 2016, and unanimously recommended 2016–17 expenditures of $52,500, and an assessment rate of $0.05 per hundredweight of dates produced or packed in Riverside County, California. In comparison, last year's budgeted expenditures were $59,250. The assessment rate of $0.05 is $0.05 lower than the rate currently in effect.

The major expenditure recommended by the committee for the 2016–17 crop year is $52,500 for general and administrative expenses. In comparison, the major expenditure recommended by the committee for the 2015–16 crop year was $59,250 for general and administrative expenses.

This year's crop is estimated to be similar in size to last year's crop. The income generated when applying the recommended lower assessment rate to the estimated crop, and combined with carry-in funds from the 2015–16 crop year and income from other sources, should be sufficient to cover anticipated 2016–17 expenses. The financial reserve will also be maintained within the limit specified under the order.

The assessment rate of $0.05 per hundredweight of dates handled was recommended by the committee after considering several factors: The anticipated size of the 2016–17 crop, the committee's estimates of the incoming reserve, other income, and anticipated expenses. Date shipments for the year are estimated at 29,000,000 pounds (290,000 hundredweight) which should provide $14,500 in assessment income. Income derived from handler assessments, funds from the committee's authorized reserve, along with other income should be adequate to cover budgeted expenses for the crop year.

Section 987.72(d) of the order states that the committee may maintain a monetary reserve not to exceed the average of one year's expenses incurred during the most recent five preceding crop years, except that an established reserve need not be reduced to conform to any recomputed average. The committee expects to utilize $33,000 of the reserve during the year to cover expenses, leaving approximately $39,500 in the reserve account at the end of the crop year. The remaining reserve will be below the limit specified in the order.

The assessment rate established in this rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the committee or other available information.

Although this assessment rate is effective for an indefinite period, the committee will continue to meet prior to or during each crop year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of committee meetings are available from the committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The committee's 2016–17 budget and those for subsequent crop years will be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 70 date producers in the production area and 11 date handlers subject to regulation under the order. The Small Business Administration defines small agricultural producers as those having annual receipts of less than $750,000, and small agricultural service firms as those whose annual receipts are less than $7,500,000. (13 CFR 121.201)

According to the National Agricultural Statistics Service (NASS), data for the most-recently completed crop year (2015) shows that about 4.36 tons, or 8,720 pounds, of dates were produced per acre. The 2015 producer price published by NASS was $1,560 per ton. Thus, the value of date production per acre in 2014–15 averaged about $6,802 (4.36 tons times $1,560 per ton, rounded to the nearest dollar). At that average price, a producer would have to farm over 110 acres to receive an annual income from dates of $750,000 ($750,000 divided by $6,802 per acre equals 110.26 acres). According to committee staff, the majority of California date producers farm less than 110 acres. Thus, it can be concluded that the majority of date producers could be considered small entities. In addition, according to data from the committee staff, the majority of California date handlers have receipts of less than $7,500,000 and may also be considered small entities.

This rule decreases the assessment rate collected from handlers for the 2016–17 and subsequent crop years from $0.10 to $0.05 per hundredweight of dates handled. The committee unanimously recommended 2016–17 expenditures of $52,500 and an assessment rate of $0.05 per hundredweight of dates, which is $0.05 lower than the 2015–16 rate currently in effect. The quantity of assessable dates for the 2016–17 crop year is estimated at 29,000,000 pounds (290,000 hundredweight). Thus, the $0.05 rate should provide $14,500 in assessment income. Income derived from handler's assessments, funds from the committee's authorized reserve, and other income should be adequate to cover expenses for the 2016–17 crop year.

The major expenditure recommended by the committee for the 2016–17 crop year is $52,500 for general and administrative expenses. The major expenditure recommended by the committee for the 2015–16 crop year was $59,250 for general and administrative expenses.

The committee recommended a lower assessment rate because they will fund only general and administrative expenses and use funds from the reserve to augment their assessments. The income generated from the lower assessment rate applied to the estimated crop, combined with carry-in funds from the 2015–16 crop year and income from other sources, should be sufficient to cover anticipated 2016–17 expenses and to maintain a financial reserve within the limit specified under the order.

Section 987.72(d) of the order states that the committee may maintain a monetary reserve not to exceed the average of one year's expenses incurred during the most recent five preceding crop years, except that an established reserve need not be reduced to conform to any recomputed average. The committee estimated a $72,500 reserve carry-in for the 2016–17 crop year. It expects to utilize $33,000 of the reserve during the year, leaving a carry-out of approximately $39,500 at the end of the 2016–17 crop year, which is below the limit specified in the order.

The committee reviewed and unanimously recommended 2016–17 crop year expenditures of $52,500. Prior to arriving at this budget, the Committee considered alternative expenditure levels and assessment rates, including not changing the assessment rate at all or varying the line item expenses. Ultimately, the committee recommended an assessment rate of $0.05 per hundredweight of dates after considering several factors including the anticipated 2016–17 crop size, the committee's estimates of the incoming reserve funds and other income, and its anticipated expenses.

A review of historical and preliminary information pertaining to the upcoming crop year indicates that the producer price for the 2015–16 crop year was approximately $78.00 per hundredweight of dates. Utilizing that price, the estimated crop size, and the assessment rate of $0.05 per hundredweight, the estimated assessment revenue for the 2016–17 crop year as a percentage of total producer revenue is approximately .00064 percent.

This action decreases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers. In addition, the committee meeting was widely publicized throughout the California date industry, and all interested persons were invited to attend the meetings and encouraged to participate in committee deliberations on all issues. Like all committee meetings, the June 22, 2016, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Industry members also discussed the various possible assessment rates, potential crop size, and estimated expenses at this meeting. Finally, interested persons are invited to submit comments on this interim rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178, "Vegetable and Specialty Crop Marketing Orders." No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This action imposes no additional reporting or recordkeeping requirements on either small or large Riverside County, California date handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The 2016–17 crop year begins on October 1, 2016, and the marketing order requires that the rate of assessment for each crop year apply to all assessable dates handled during such crop year; (2) the action decreases the assessment rate for assessable dates beginning with the 2016–17 crop year; (3) handlers are aware of this action which was unanimously recommended by the committee at a public meeting and is similar to other assessment rate actions issued in past years; and (4) this interim rule provides a 60-day comment period, and all comments timely received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 987

Dates, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 987 is amended as follows:

PART 987—DOMESTIC DATES PRODUCED OR PACKED IN RIVERSIDE COUNTY, CALIFORNIA

■ 1. The authority citation for 7 CFR part 987 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 987.339 is revised to read as follows:

§ 987.339 Assessment rate.

On and after October 1, 2016, an assessment rate of $0.05 per hundredweight is established for dates produced or packed in Riverside County, California.

Dated: September 16, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–22745 Filed 9–20–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2016–N–2562]

Medical Devices; General and Plastic Surgery Devices; Classification of the Magnetic Surgical Instrument System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Magnetic Surgical Instrument System into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the magnetic surgical instrument system's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective September 21, 2016. The classification was applicable on June 13, 2016.

FOR FURTHER INFORMATION CONTACT: Varun Pattani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G452, Silver Spring, MD, 20993–0002, 301–796–6368, *varun.pattani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of "low-moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On February 9, 2015, Levita Magnetics International Corp., submitted a request for classification of the Levita Magnetic Surgical System under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 13, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4815.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a magnetic surgical instrument system will need to comply with the special controls named in this final order. The device is assigned the generic name magnetic surgical instrument system, and it is identified as a prescription device used in laparoscopic surgical procedures consisting of several components, such as surgical instruments, and a magnetic controller. The magnetic controller is provided separately from the surgical instrument and is used outside the patient. The external magnetic controller is magnetically coupled with the internal surgical instrument(s) at the surgical site to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks in table 1.

TABLE 1—MAGNETIC SURGICAL INSTRUMENT SYSTEM RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Tissue Damage	In vivo Performance Testing. Human Factors Testing and Analysis. Training. Labeling.
Need for Extended or Additional Surgery: • Inability to couple the external magnet with the internal surgical instrument • Inability to retrieve or maneuver device • Inability to visualize critical anatomical structures	In vivo Performance Testing. Non-clinical Performance Testing. Human Factors Testing and Analysis. Training. Labeling.
Abdominal Wall Injury	In vivo Performance Testing. Human Factors Testing and Analysis. Labeling.
Electromagnetic Field Incompatibility or Interference (including ferromagnetic implants in users and patients, electrosurgical devices, etc.).	Non-clinical Performance Testing. Human Factors Testing and Analysis. Training. Labeling.
Adverse Tissue Reaction	Biocompatibility Evaluation.
Infection	Sterilization Validation. Reprocessing Validation. Shelf Life Validation. Labeling.

FDA believes that the special controls, in addition to the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

A magnetic surgical instrument system device is not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, *Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the magnetic surgical instrument system they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 878.4815 to subpart E to read as follows:

§ 878.4815 Magnetic surgical instrument system.

(a) *Identification.* A magnetic surgical instrument system is a prescription device used in laparoscopic surgical procedures consisting of several components, such as surgical instruments, and a magnetic controller. The magnetic controller is provided separately from the surgical instrument and is used outside the patient. The external magnetic controller is magnetically coupled with the internal surgical instrument(s) at the surgical site to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) In vivo performance data must demonstrate that the device performs as intended under anticipated conditions of use. Testing must demonstrate the ability of the device to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.

(2) Non-clinical performance data must demonstrate that the system performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Magnetic field strength testing characterization to identify the distances from the magnet that are safe for patients and users with ferromagnetic implants, devices, or objects.

(ii) Ability of the internal surgical instrument(s) to be coupled, de-coupled, and re-coupled with the external magnet over the external magnet use life.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components that are patient-contacting.

(5) Methods and instructions for reprocessing reusable components must be validated.

(6) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components and device functionality over the labeled shelf life.

(7) Training must be developed and validated by human factors testing and analysis to ensure users can follow the instructions for use to allow safe use of the device.

(8) Labeling must include:

(i) Magnetic field safe zones.

(ii) Instructions for proper device use.

(iii) A screening checklist to ensure that all patients and operating staff are screened from bringing ferromagnetic implants, devices, or objects near the external magnet.

(iv) Reprocessing instructions for any reusable components.

(v) Shelf life.

(vi) Use life.

Dated: September 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22709 Filed 9–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 5

[Docket No. FR 5863–F–02]

RIN 2506–AC40

Equal Access in Accordance With an Individual's Gender Identity in Community Planning and Development Programs

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: Through this final rule, HUD ensures equal access for individuals in accordance with their gender identity in programs and shelter funded under programs administered by HUD's Office of Community Planning and Development (CPD). This rule builds upon HUD's February 2012 final rule entitled "Equal Access to Housing in HUD Programs Regardless of Sexual Orientation or Gender Identity" (2012 Equal Access Rule), which aimed to ensure that HUD's housing programs would be open to all eligible individuals and families regardless of sexual orientation, gender identity, or marital status. The 2012 Equal Access Rule, however, did not address how transgender and gender non-conforming individuals should be accommodated in temporary, emergency shelters, and other buildings and facilities used for shelter, that have physical limitations or configurations that require and that are permitted to have shared sleeping quarters or shared bathing facilities. This final rule follows HUD's November 2015 proposed rule, which addressed

this issue and solicited public comment on measures to ensure that recipients and subrecipients of CPD funding—as well as owners, operators, and managers of shelters and other buildings and facilities and providers of services funded by CPD—grant equal access to such facilities and services to individuals in accordance with an individual's gender identity.

This rule amends HUD's definition of "gender identity" to more clearly reflect the difference between actual and perceived gender identity and eliminates the prohibition on inquiries related to sexual orientation or gender identity, so that service providers can ensure compliance with this rule. The removal of the prohibition on inquiries related to sexual orientation or gender identity does not alter the requirement to make housing assisted by HUD and housing insured by the Federal Housing Administration (FHA) available without regard to actual or perceived sexual orientation or gender identity. Lastly, without changing the scope of the requirement to provide equal access without regard to sexual orientation, this rule makes a technical amendment to the definition of "sexual orientation," which HUD adopted from the Office of Personnel Management's (OPM) definition of the term in 2012, to conform to OPM's current definition.

In order to ensure that individuals are aware of their rights to equal access, HUD is publishing elsewhere in this issue of the **Federal Register** for public comment, in accordance with the Paperwork Reduction Act of 1995, a document entitled "Equal Access Regardless of Sexual Orientation, Gender Identity, or Marital Status" for owners or operators of CPD-funded shelters, housing, facilities, and other buildings to post on bulletin boards and in other public spaces where information is typically made available.

DATES: *Effective:* October 21, 2016.

FOR FURTHER INFORMATION CONTACT: Norm Suchar, Director, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410–7000; telephone number 202–708–4300 (this is not a toll-free number). Persons with who are deaf or hard of hearing or have speech impairments can access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

A. HUD's Previous Efforts To Ensure Equal Access

On February 3, 2012, at 77 FR 5662, HUD issued its 2012 Equal Access Rule, which defined the terms "sexual orientation" and "gender identity," and required that HUD-assisted housing, including all housing funded by CPD, and housing insured by FHA be made available to individuals and families without regard to actual or perceived sexual orientation, gender identity, or marital status. The 2012 Equal Access Rule also generally prohibited inquiries into sexual orientation or gender identity for the purpose of determining eligibility for, or availability of, such housing. In the 2012 Equal Access Rule, HUD declined to adopt a national policy on the placement of transgender persons in temporary, emergency shelters with shared sleeping quarters or shared bathing facilities, deciding instead to conduct research and monitor its programs to determine whether additional guidance or national policy was needed to ensure equal access for transgender and gender nonconforming persons.[1] HUD also decided to conduct a similar review to determine whether additional guidance was needed with regard to the prohibition on inquiries.

As a result of its review, HUD determined that the 2012 Equal Access Rule did not adequately address the significant barriers faced by transgender and gender nonconforming persons when accessing temporary, emergency shelters and other facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or bathing facilities. Specifically, HUD found that transgender and gender nonconforming persons continue to experience significant violence, harassment, and discrimination in attempting to access programs, benefits, services, and accommodations. For instance, at a listening session on lesbian, gay, bisexual, and transgender (LGBT) issues conducted with the U.S. Interagency Council on Homelessness, homeless service providers reported that transgender persons are often discriminatorily excluded from shelters or face dangerous conditions in the shelters that correspond to their sex assigned at birth. Some commenters reported that, if given the choice between a shelter designated for assigned birth sex or sleeping on the streets, many transgender shelter-seekers would choose the streets.

HUD also investigated individual cases where transgender persons were not provided equal access as required by the 2012 Equal Access Rule, or they faced unlawful discrimination under the Fair Housing Act. HUD also reviewed national research that revealed that lack of access to shelter for transgender and gender nonconforming persons, particularly those who were also homeless youths, was a pervasive problem and reviewed the efforts of other Federal agencies to provide equal access to transgender and gender nonconforming persons. HUD found that multiple agencies prohibit discrimination on the basis of sexual orientation and gender identity and also require that grant recipients treat transgender persons consistent with their gender identity. Specifically, HUD found guidance from other Federal agencies supporting the position that grant recipients could accommodate transgender individuals in accordance with their gender identity in Federal programs, including those program that funded single-sex facilities.

On February 20, 2015, CPD issued guidance, entitled "Appropriate Placement for Transgender Persons in Single-Sex Emergency Shelters and Other Facilities" (CPD–15–02), which applied to the following CPD programs: Housing Opportunities for Persons With AIDS (HOPWA), Emergency Solutions Grants (ESG), and Continuum of Care (CoC). This guidance clarified that HUD expected recipients and subrecipients under these programs to base placement decisions on the gender with which a person identifies—and not on another person's stereotype-based complaints—taking into consideration health and safety concerns and giving serious consideration to the transgender or gender nonconforming person's own personal health and safety concerns. The guidance also outlined best practices for providers.

B. The November 2015 Proposed Rule

On November 20, 2015, at 80 FR 72642, following careful review of information about the treatment of transgender persons in temporary, emergency shelters, HUD proposed a second Equal Access rule, entitled "Equal Access in Accordance with an Individual's Gender Identity in Community Planning and Development Programs" (CPD Equal Access). In this rulemaking, HUD proposed to add a new section to its regulations in 24 CFR part 5 that would require recipients and subrecipients of assistance under CPD programs—as well as owners, operators, and managers of shelters and other buildings and facilities and providers of services funded in whole or in part by CPD programs—to provide equal access to programs, benefits, services, and accommodations in accordance with an individual's gender identity.

---

[1] Gender nonconforming persons are persons who do not follow other people's ideas or stereotypes about how they should look or act based on their sex assigned at birth.

Specifically, the rule proposed to add to 24 CFR part 5 a new § 5.106, which would contain equal access provisions tailored to CPD programs. Section 5.106(a) proposed to identify the scope of its coverage as including recipients and subrecipients of assistance under the following CPD programs: HOME Investment Partnerships (HOME) (24 CFR part 92), Community Development Block Grant (CDBG) (24 CFR part 570), HOPWA (24 CFR part 574), ESG (24 CFR part 576), CoC (24 CFR part 578), as well as owners, operators, managers of shelters and other buildings and facilities and providers of services funded in whole or in part by any of these programs.

Section 5.106(b) proposed to require CPD recipients, subrecipients, owners, operators, managers, and providers to establish or amend, as necessary, and administer program admissions, occupancy, and operating policies and procedures, including policies and procedures to protect individuals' privacy and security, so that equal access to programs, shelters, other buildings and facilities, benefits, services, and accommodations are provided to individuals in accordance with their gender identity. That section also proposed to require that such equal access be provided in a manner that affords equal access to the individual's family.

Section 5.106(c) proposed to require that the placement and accommodation of individuals in facilities that are permitted to be single-sex must be made in accordance with the individual's gender identity. The proposed rule provided that, under narrow circumstances, a written case-by-case determination could be made as to whether an alternative accommodation is necessary to ensure health and safety. The proposed rule contained a prohibition for such a determination to be based solely on a person's actual or perceived gender identity or on complaints of other shelter residents when those complaints are based on actual or perceived gender identity. It also proposed to prohibit the denial of appropriate placement based on a perceived threat to health or safety that can be mitigated some other, less burdensome way (*e.g.*, by providing the transgender shelter seeker the option to use single occupant bathing facilities). Lastly, the rule proposed that, to avoid unwarranted denials of placement in accordance with an individual's gender identity, decisions to provide accommodations based on concern for the health and safety of the individual seeking accommodations should be based on the individual's own request to be otherwise accommodated.

Section 5.106(d) proposed to require that when a case-by-case determination based on health and safety is made under § 5.106(c), the entity providing the alternative accommodation must provide either (1) equivalent alternative accommodation, benefits, and services or (2) a referral to a comparable alternative program with availability that meets the needs of the individual.

Section 5.106(e) proposed to require recipients, subrecipients, or providers to keep records of compliance with paragraphs (b) and the case-by-case determinations under paragraph (c) of this section, including the facts, circumstances, and reasoning relied upon that lead to any alternative admission, accommodation, benefit, or service to an individual and the individual's family; the facts and circumstances regarding the opportunities to access alternative accommodations provided to an individual and the individual's family; and the outcomes regarding referral to an alternative program of an individual and the individual's family.

In addition, the rule proposed to amend the definition of "gender identity" at § 5.100 to separate the definitions of "actual" and "perceived" gender identity. In brief, the rule proposed to replace HUD's current definition, which mirrored the definition in the Matthew Shepard/James Byrd Hate Crimes Prevention Act of 2009 (Public Law 114–38, approved October 28, 2009) and instead adopt a definition that clarified the difference between actual and perceived gender identity.

Lastly, the proposed rule sought to remove the prohibition on inquiries provision at § 5.105(a)(2)(ii), which prohibited providers in most circumstances from asking individuals their sexual orientation or gender identity. HUD reasoned that the provision raised several legitimate questions about implementation, and its removal would allow temporary, emergency shelters or other buildings and facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities to ask an individual's gender identity for nondiscriminatory purposes, such as to determine the appropriate placement for the individual or the number of bedrooms to which a household is entitled.

C. Recent Developments in the Interpretation of Federal Law and Applicable Research

After HUD issued the November 2015 proposed rule, the Center for American Progress released a new study specifically focusing on discrimination experienced by transgender individuals seeking access to shelters, the Department of Justice (DOJ) and the Department of Education issued guidance for educators on providing equal access for transgender students in schools, and the Department of Health and Human Services issued a final rule to ensure equal access to health programs and activities administered by that Department or established under title I of the Affordable Care Act.

On January 7, 2016, the Center for American Progress released the results of a discrimination telephone test, carried out across four States, that measured the degree to which transgender homeless women can access a shelter in accordance with their gender identity, as well as the types of discrimination and mistreatment they face in the process.[2] The study consisted of 100 phone calls to homeless shelters in four States, over 3 months, by testers who identified themselves as transgender women seeking access to both women's shelters and general shelters. The study found that only 30 percent of the shelters contacted by the testers were willing to house the transgender women with other women, 13 percent offered to house the transgender women in isolation or with men, 21 percent refused service altogether, and another 21 percent were unsure or unclear as to whether they could house transgender women with other women. The survey results also found that women's shelters were more likely to provide services consistent with an individual's gender identity than were mixed gender shelters. During interactions on the phone with shelter employees, testers experienced the following: they were often referred to using the wrong gender or shelter employees made other statements to discredit their gender identity, shelter employees made references to the testers' genitalia or to surgery as requirements for appropriate housing, and shelter employees stated that other residents would be made uncomfortable or unsafe by the tester. Of the shelters called, 27 percent had received HUD funds at some point.

---

[2] Caitlin Rooney, et al., Center for American Progress and the Equal Rights Center *Discrimination Against Transgender Women Seeking Access to Homeless Shelters,* January 7, 2016, available at: *https://cdn.americanprogress.org/wp-content/uploads/2016/01/06113001/HomelessTransgender.pdf.*

In May 2016, DOJ and the Department of Education released guidance summarizing the legal obligations of schools regarding transgender students.[3] The guidance specifically emphasizes that schools must "treat a student's gender identity as the student's sex for purposes of Title IX and its implementing regulations." In sex-segregated activities and facilities, transgender students "must be allowed to participate in such activities and access such facilities consistent with their gender identity." The guidance also requires schools to provide a safe environment for all students, including transgender students, and requires that schools treat students consistent with their gender identity regardless of records or identification documents indicating a different sex.

Also in May 2016, the Department of Health and Human Services issued final regulations entitled "Nondiscrimination in Health Programs and Activities," which implement section 1557 of the Affordable Care Act.[4] Section 1557 prohibits discrimination in health programs and activities on the basis of sex, and the rule provides that "a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available."

II. Changes Made at the Final Rule Stage

In response to public comment and upon further consideration by HUD of the issues presented in this rulemaking, HUD makes the following changes at this final rule stage:

In § 5.100, the proposed definition of "perceived gender identity" is modified so that the definition states that "perceived gender identity" means the gender with which a person is perceived to identify based on that person's appearance, behavior, expression, other gender-related characteristics, sex assigned at birth, or identification in documents. This change was made in response to public comments stating that transgender persons often face difficulty in being accommodated in accordance with their gender identity because it is difficult to obtain identity documents that accurately list their gender identity. The words "identified in documents" were added to the definition to make clear that the identification of gender or sex on an individual's identity document may be different than a person's actual gender identity. The definition of "gender identity" in the final rule, which is unchanged from the proposed rule, makes clear that "gender identity" means the gender with which a person identifies, regardless of the sex assigned to that person at birth and regardless of the person's perceived gender identity. Reading these definitions together, "gender identity" is therefore determined regardless of the gender identified on an individual's identity documents.

This rule also makes a technical amendment to the definition of "sexual orientation." The 2012 Equal Access Rule defined "sexual orientation" as "homosexuality, heterosexuality, or bisexuality," following a definition that OPM used in the context of the Federal workforce in its publication "Addressing Sexual Orientation in Federal Civilian Employment: A Guide to Employee Rights." OPM's publication was revised in June 2015, and HUD is amending its definition to conform to the new OPM definition, which is "sexual orientation means one's emotional or physical attraction to the same and/or opposite sex." (See *https://www.opm.gov/policy-data-oversight/diversity-and-inclusion/reference-materials/addressing-sexual-orientation-and-gender-identity-discrimination-in-federal-civilian-employment.pdf.*) This change in definition does not change the coverage provided by the prior definition but is simply intended to use terminology that is up-to-date.

In § 5.105(a)(2), HUD adopts the proposal to eliminate the inquiries provision in § 5.105(a)(2)(ii). With the removal of § 5.105(a)(2)(ii), § 5.105(a)(2)(i) is redesignated as § 5.105(a)(2).

In § 5.106, HUD makes several changes. HUD has changed the heading of this section from "Providing access in accordance with the individual's gender identity in community planning and development programs" to "Equal access in accordance with the individual's gender identity in community planning and development programs." Although this is not a substantive change, the change appropriately emphasizes that the purpose of the rule is equal access in accordance with an individual's gender identity in CPD programs generally. Equal access ensures that, when consideration of sex is prohibited or not relevant, individuals will not be discriminated against based on actual or perceived gender identity, and where legitimate consideration of sex or gender is appropriate, such as in a facility providing temporary, short term shelter that is not covered by the Fair Housing Act[5] and which is legally permitted to operate as a single-sex facility,[6] the individual's own self-identified gender identity will govern.

Section 5.106(a) is revised at the final rule stage to clarify that § 5.106 applies to recipients and subrecipients of assistance from CPD, which include the specific programs identified at the proposed rule stage (HOME, CDBG, HOPWA, ESG, and CoC), as well as to the Housing Trust Fund program (with regulations at 24 CFR part 93) and the Rural Housing Stability Assistance Program (with regulations to be codified in 24 CFR part 579). As noted throughout the proposed rule, the rule was always intended to apply to recipients and subrecipients of CPD programs, as well as those who administer programs and services and provide temporary, emergency shelter funded by CPD programs, and HUD did not intend to exclude the new Housing Trust Fund and Rural Housing Stability

---

[3] Dear Colleague Letter on Transgender Students May 13, 2016, *https://www.justice.gov/opa/file/850986/download.*

[4] See 81 FR 31375, *https://www.federalregister.gov/articles/2016/05/18/2016-11458/nondiscrimination-in-health-programs-and-activities.*

[5] The Fair Housing Act prohibits discrimination in the sale, rental, making unavailable, or financing of dwellings and in other housing-related activities on the basis of race, color, religion, sex, disability, familial status, and national origin, and thus prohibits making housing unavailable to a person because of that person's sex. 42 U.S.C. 3601 *et seq.* The Fair Housing Act contains no exemptions that permit covered housing to be sex-segregated. *See* 42 U.S.C. 3603(b) (limited exemptions from Fair Housing Act coverage for sales of certain single family homes and for rooms or units in certain owner-occupied dwellings), and § 3607 (exemptions from Fair Housing Act coverage for private clubs and religious organizations).

[6] Temporary, emergency shelters and other buildings and facilities that are not covered by the Fair Housing Act because they provide short-term, temporary accommodations may provide sex-segregated accommodations, which they sometimes do to protect the privacy and security of individuals when the buildings and facilities have physical limitations or configurations that require shared sleeping quarters or shared bathing facilities. For purposes of this rule, shared sleeping quarters or shared bathing facilities are those that are designed for simultaneous accommodation of multiple individuals in the same space. For example, a single-user bathing facility with a lock on the door is not designated for simultaneous occupancy by multiple individuals, so it is not a "shared bathing facility" for purposes of the Equal Access Rule or this rule.

Assistance programs from the list of CPD programs in this paragraph.

Section 5.106(b) addresses the admissions, occupancy, and operating policies and procedures of recipients, subrecipients, owners, operators, managers, and providers covered by this rule. Revised paragraph (b) adds that policies and procedures to protect health and safety, as well as privacy and security noted in the proposed rule, must be established, maintained, or amended, as necessary, and provides that all policies must be administered in a nondiscriminatory manner. HUD recognizes that in the temporary, emergency shelters covered by this rule, privacy, security, safety, and health concerns may arise as a result of the varied populations that reside in such facilities at any given time. The rule requires policies and procedures, if such policies and procedures have not already been updated, to reflect the obligation and to document the commitment of the provider to maintain a healthy and safe environment for all occupants and respect individual privacy without doing so in a way that is discriminatory or violates applicable Federal laws and regulations.

HUD also revises paragraph (b) to add a provision that the policies and procedures must ensure that individuals are not subjected to intrusive questioning or asked to provide anatomical information or documentary, physical, or medical evidence of the individual's gender identity. This revision was made in response to public comment advising that transgender persons and gender nonconforming persons are often asked inappropriate, intrusive questions; asked to provide evidence about their physical anatomy; or asked for medical records relating to their gender identity or identification documents that record their gender identity. There are multiple reasons why this documentation is problematic and prohibited by this rule. Homeless persons encounter difficulties in maintaining their identification documents, and individuals whose gender identities differ from sex assigned at birth experience varying levels of difficulty in updating gender markers on identification documents. These barriers make it likely that an individual seeking homeless services and whose gender identity differs from their sex assigned at birth will possess identification documents that do not reflect that individual's gender identity, if they have identification documents at all. Further, gender identity is distinct from sex assigned at birth, is not associated with physical anatomy, and may not be indicated in medical records. For these reasons, HUD agrees with public commenters that it is important that transgender or gender nonconforming persons can self-identify their gender identity orally and not be asked intrusive questions or asked to provide documentary, physical, or medical evidence to prove their gender identity.

Lastly, revised paragraph (b) also requires that such revisions ensure that amendments to CPD programs policies and procedures continue to include the existing requirement in § 5.105(a)(2) that individuals are provided equal access to housing in CPD programs without regard to actual or perceived gender identity. While this rule's focus is on programs, owners, operators, and managers of shelters, buildings, and other facilities and providers of CPD-funded services that were not covered under HUD's 2012 Equal Access Rule, housing under CPD programs has already been required to ensure equal access to individuals based on their gender identity. HUD adds this provision to clarify that, when amending CPD program policies and procedures, they should continue to reflect the existing 2012 Equal Access Rule requirement that housing be made available without regard to gender identity.

In § 5.106(c), which addresses placement and accommodation in temporary, emergency shelters and other buildings and facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities, HUD removes the proposed rule language that under narrow circumstances, a written case-by-case determination could be made on whether an alternative accommodation for a transgender individual would be necessary to ensure health and safety. Public commenters expressed concern that the exception could be inappropriately used to avoid compliance with the equal access requirement, and that this "exception" also targeted transgender individuals as a cause of concern with respect to health and safety. HUD was persuaded by the public commenters that the "exception" provision had the opposite effect than that intended by HUD. HUD's intention in the inclusion of this language was to strive to ensure the health and safety of transgender individuals in temporary, emergency shelters and other buildings and facilities. It was not to indicate that the very presence of transgender individuals was a cause for health and safety concerns nor to indicate, by allowing alternative accommodation, that HUD's only concern was the health and safety of transgender individuals and HUD was not concerned about any other occupants. HUD's regulations for the ESG program and the implementing guidance, make clear that temporary, emergency shelters, and other buildings and facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities have had, and continue to have, a responsibility to create a safe environment for all occupants, particularly those of special populations (see 24 CFR 576.400(e)(3)(iii) for more information).

This final rule thus revises paragraph (c) of § 5.106 to provide that placement and accommodation of individuals shall be made in accordance with an individual's gender identity, and it removes language that permits an exception to this rule where a provider makes a written case-by-case determination on whether an alternative accommodation for a transgender individual would be necessary to ensure health and safety. There are various measures that HUD's providers may take to fulfill their duty to create a safe environment for all, including transgender and gender nonconforming individuals, and to ensure that HUD-funded projects are free from discrimination. As preemptive steps, providers are strongly encouraged to post a notice of rights under this rule and under HUD's 2012 Equal Access Rule on bulletin boards and in other public spaces where information is made available, to clearly establish expectations. In order to ensure that individuals are aware of their rights to equal access, HUD proposes to require owners and operators of CPD-funded shelters and facilities to post on bulletin boards and in other public spaces where information is typically made available a notice entitled "Equal Access Regardless of Sexual Orientation, Gender Identity, or Marital Status for HUD's Community Planning and Development Programs," which HUD is publishing in today's **Federal Register** for public comment, in accordance with the Paperwork Reduction Act of 1995. In addition, HUD Technical Assistance materials provide a sample antidiscrimination policy that providers may consider adopting to further clarify expectations to persons as they enter the project.[7]

---

[7] See *Equal Access for Transgender People: Supporting Inclusive Housing and Shelters https://www.hudexchange.info/resources/documents/Equal-Access-for-Transgender-People-Supporting-Inclusive-Housing-and-Shelters.pdf.*

Even with antidiscrimination policies clearly articulated, occupants may express concerns or engage in other behavior toward transgender or gender nonconforming persons. If some occupants initially present concerns about transgender or gender nonconforming occupants to project staff and managers, staff should treat those concerns as opportunities to educate and refocus the occupants. HUD recognizes that, even then, conflicts may persist and complaints may escalate to verbal or physical harassment. In these situations, providers should have policies and procedures in place to support residents and staff in addressing and resolving conflicts that escalate to harassment. These policies should include specific behaviors that violate standards of respectful behavior, escalate corrective actions if an individual repeats the same violation of standards after educational opportunities are offered, and focus corrective actions on aggressors who violate project rules, not on the person targeted by the harassment. If an occupant continues to harass a transgender individual, the provider should consider requiring that the harassing occupant stay away from the transgender individual, making changes in sleeping arrangements without limiting the freedom of the transgender individual, or pursuing other interventions. When appropriate, providers may consider expelling harassing residents, or any staff or volunteer members who perpetuate discrimination. In no instance, however, should any steps taken to address harassment or discrimination involve expulsion of harassed occupants.

Revised paragraph (c) provides for post-admission accommodations, where after an individual has been admitted to a temporary, emergency shelter, or other building or facility with shared sleeping quarters or shared bathing facilities, the provider must take non-discriminatory steps that may be necessary and appropriate to address privacy concerns raised by all residents or occupants, and, as needed, update its admissions, occupancy, and operating policies and procedures. These provisions apply to all individuals, regardless of gender identity. If an individual requests certain accommodations because of privacy concerns, staff may offer those accommodations to that individual but may not require that the individual use the accommodations. For example, if available, staff may offer that occupant a room, floor, or bed that is close to staff workstations or access to rooms, floors, or beds set aside for residents with increased vulnerability. At the request of an individual, providers may also offer use of a single-occupant bathroom or provide certain times during the day that a shared bathroom can be scheduled by any client with a request to use a private bathing facility. If feasible, providers can ensure that toilet and shower stalls have locking doors or, at a minimum, curtains to allow for modesty and privacy. For shower use, providers may consider implementing a schedule for all clients if communal showers are the only available type of shower. HUD stresses that all such accommodations should be offered only to fulfill the request of individuals seeking accommodations for themselves, should be available to clients based on a variety of factors that can increase one's vulnerability, and should not be restricted for use only by transgender or gender nonconforming residents. In no case may a provider's policies isolate or segregate transgender or gender nonconforming occupants.

This final rule removes from § 5.105(d) in the proposed rule the language relating to referrals, HUD has removed the provision from the proposed rule that permitted housing providers to make a written case-by-case determination that a transgender individual should receive an alternative accommodation for health and safety reasons. This does not preclude the possibility that any occupant may request a referral to an alternate project for health and safety reasons, and in such cases staff may provide a referral or offer clients a hotel or motel voucher.[8]

This final rule redesignates the recordkeeping requirements from § 5.106(e) to 5.106(d) and states that providers must document and maintain, for a period of 5 years, records of compliance with the requirements of this rule regarding establishing or amending policies and procedures. This rule also removes the more specific requirements related to case-by-case determinations and referrals.

To strengthen enforcement mechanisms for this rule, HUD is publishing in today's **Federal Register** a notice for public comment, in accordance with the Paperwork Reduction Act of 1995, entitled "Equal Access Regardless of Sexual Orientation, Gender Identity, or Marital Status for HUD's Community Planning and Development Programs." HUD proposes to require owners and operators of CPD-funded shelters and facilities to post this notice on bulletin boards and in other public spaces where information is typically made available.

III. Public Comments Submitted on Proposed Rule and HUD's Responses

A. Overview of Public Comments

The public comment period for the November 20, 2015, proposed rule closed on January 19, 2016. As of the close of the comment period, HUD received approximately 184 public comments, in addition to a number of mass mailings, from a variety of commenters, including housing authorities, direct legal services providers, community development agencies, homeless shelters, healthcare providers, social workers, clergy, counselors, nonprofit social service providers, and LGBT advocacy organizations. The overwhelming majority of comments were supportive of the rule. Some commenters, while supporting the rule, suggested modifications, and a minority of the commenters opposed the rule. Commenters opposing the rule stated that it failed to balance the needs of all shelter occupants and lacks flexibility. All comments can be viewed at *http://www.regulations.gov.*

1. Commenters Supporting the Rule

Many commenters supporting the rule suggested no changes and offered a variety of reasons why they supported the rule and why HUD should conclude the rulemaking as expeditiously as possible. Commenters stated that transgender persons, like all persons, need access to safe shelter and housing and that transgender persons are some of the most vulnerable members of society. Commenters stated that transgender individuals are disproportionately represented in the homeless population because of the frequent discrimination they face at home, in school, and on the job. Some cited a survey showing that one in five transgender or gender nonconforming individuals experienced homelessness at some point in their lives because of their transgender status. Commenters stated that transgender individuals were at greater overall risk of violence, murder, and homelessness-related death than people who are not transgender and may also experience mental and physical health problems because of the abuse they face.

Commenters stated that the rule would promote civil rights and expanded housing opportunity by addressing the effects of stigma on equal access to housing for transgender and gender nonconforming persons. Commenters supporting the rule frequently stated that the rule would eliminate major barriers to access to safe, temporary, emergency shelter and other facilities and programs for transgender and gender nonconforming persons, particularly vulnerable subgroups within the population that need access to such accommodations. Some commenters stated that the rule will yield other positive societal outcomes. Many commenters provided extensive data to support the rule, including a January 2016 study conducted by the Center for American Progress that found, among other things, that only 30 percent of shelters studied were willing to accommodate transgender women in accordance with their gender identity. The commenters stated that LGBT providers were twice as likely to be willing to provide a shelter-seeker with accommodations in accordance with the individual's gender identity; that women's shelters were more likely than mixed-gender shelters to provide a shelter-seeker with accommodations in accordance with the individual's gender identity; and that many shelters did not correctly classify shelter-seekers in accordance with the individual's gender identity or stated that transgender or gender nonconforming individuals would have to submit to invasive medical examinations or inquiries, or demonstrate that they had undergone surgery, as a prerequisite to obtaining shelter.[9]

---

[8] In the ESG program, a hotel or motel voucher may be offered only if there are no other accessible or appropriate emergency shelter beds available for that night.

Other commenters supporting HUD's rule stated that the rule is needed because the willingness to house transgender people in accordance with their gender identity currently varies, depending on State laws and shelter type, and HUD's rule would provide some consistency. Commenters stated that because 32 States lack explicit gender identity protections in housing, HUD's rule will help ensure equal access to shelters nationwide for transgender and gender nonconforming individuals. Commenters said that even in jurisdictions with express protections for transgender individuals, discriminatory practices still persist. Commenters stated that HUD's rule is in step with recent Federal case law holding that discrimination on the basis of sexual orientation and gender identity constitutes unlawful discrimination on the "basis of sex," in violation of Title VII of the Civil Rights Act and Title IX of the Education Amendments of 1972.

2. Comments Opposing the Rule

Commenters opposing the rule provided many reasons for their opposition but the primary reason concerned the safety of nontransgender individuals in a shelter. Commenters stated that the rule should not open female, single-sex spaces to individuals who were born male, citing their fear that individuals could deliberately misrepresent their gender identities and compromise the privacy or safety of vulnerable women and children. Commenters stated that there is a risk of causing female survivors of male-perpetrated domestic or sexual violence, who are disproportionately represented in the homeless population and shelters, to feel unsafe. Commenters said the rule does not respect legitimate safety and privacy concerns of biological women, and that the rule treats women's fear of being assaulted in a shelter as unreasonable "bigotry." Commenters stated that the rule should require providers to create segregated facilities for transgender individuals, rather than placing individuals into male or female facilities that correspond to the individual's gender identity. Commenters stated that transgender men are also vulnerable to assault in shelters. Several commenters opposing the rule cited to articles recounting the stories of individuals who had been raped in shelters. A commenter stated that it is untrue that transgender women can be safe only in a women's shelter. Commenters stated that the rule must balance the various needs, perspectives, personal histories, and expectations of privacy of both transgender individuals and other shelter seekers. Commenters stated that the rule should provide equal consideration to the health and safety concerns of transgender and nontransgender individuals and guidelines on what constitutes threats to health and safety for transgender and nontransgender individuals.

3. Responses to Comments in Support and Opposition

HUD appreciates all of the comments offered in response to HUD's proposed rule. Comments supporting the rule as well as comments opposing the rule gave HUD much to consider in the development of this final rule. While HUD is proceeding with this rulemaking, HUD is making the changes highlighted in Section II of this preamble.

B. Significant Public Comments and HUD's Responses

This section presents significant issues raised by commenters and HUD's responses to these comments. The issues presented in this section highlight changes requested by commenters, and questions about or requests for clarifications about certain provisions of the rule.

Comment: Commenters stated that the rule exceeds HUD's current statutory mandate because Congress has not given HUD the authority to prohibit discrimination based on gender identity. Commenters stated that the rule's definitions of "gender identity" and "perceived gender identity" are overbroad and exceed HUD's authority by creating a new protected class and that HUD failed to specify the basis for this prohibition of discrimination.

HUD Response: The rule creates additional program requirements to ensure equal access for transgender and gender nonconforming persons, in accordance with their gender identity, in shelters, buildings, facilities, and programs funded in whole or in part by CPD. The creation of such program requirements is well within the scope of HUD's authority. HUD's mission is to create strong, sustainable, inclusive communities and quality affordable homes for all. This mission encompasses providing shelter for transgender and gender nonconforming persons, who have faced significant difficulty in obtaining access to shelters, and buildings and facilities that provide shelter. Excluding any eligible person from HUD-funded temporary, emergency shelters, buildings, facilities, housing, or programs because of that person's gender identity or nonconformance with gender stereotypes would contravene HUD's responsibility under the Department of Housing and Urban Development Act to work to address "the needs and interests of the Nation's communities and of the people who live and work in them." (See 42 U.S.C. 3531.) Congress has repeatedly charged HUD with serving the existing housing needs of all Americans.[10]

Congress has not only given HUD this broad mission but also given HUD broad authority to fulfill this mission and implement its responsibilities through rulemaking. Section 7(d) of the Department of Housing and Urban

---

[9] Center for American Progress, *Discrimination Against Transgender Women Seeking Access to Homeless Shelters* (Jan. 7, 2016), *available at https://cdn.americanprogress.org/wp-content/uploads/2016/01/06113001/HomelessTransgender.pdf*.

[10] See section 2 of the Housing Act of 1949 (42 U.S.C. 1441); section 2 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701t), sections 101 and 102 of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 12701–702), and section 2(b) of the Housing and Community Development Act of 1974 (42 U.S.C. 5301 note).

Development Act specifically states that the Secretary "may make such rules and regulations as may be necessary to carry out his functions, powers, and duties." Moreover, as discussed in the preamble to HUD's 2012 Equal Access Rule and as discussed in greater detail in response to the following comment, HUD is charged with administering and enforcing the Fair Housing Act, which prohibits discrimination on the basis of protected characteristics, including sex. Discrimination because of gender identity is covered within the Fair Housing Act's prohibition of sex discrimination. In 2010, HUD issued a memorandum recognizing that sex discrimination includes discrimination because of gender identity. In 2012, the Equal Employment Opportunity Commission (EEOC) reached the same conclusion with regard to gender identity claims, "clarifying that claims of discrimination based on transgender status, also referred to as claims of discrimination based on gender identity, are cognizable under Title VII's sex discrimination prohibition." [11] Following the EEOC's decision, the U.S. Attorney General also concluded that:

> the best reading of Title VII's prohibition of sex discrimination is that it encompasses discrimination based on gender identity, including transgender status. The most straightforward reading of Title VII is that discrimination "because of . . . sex" includes discrimination because an employee's gender identification is as a member of a particular sex, or because the employee is transitioning, or has transitioned, to another sex.[12]

HUD reaffirms its view that discrimination based on gender identity is sex discrimination.

Comment: HUD received comments on sex discrimination under the Fair Housing Act and the proposed requirement that individuals be provided accommodations in accordance with their gender identity. A commenter stated that, while it is helpful that HUD already considers the Fair Housing Act's provision against discrimination on the basis of sex to cover nonconforming gender expression, it would be helpful to make that protection explicit in the new rule.

HUD Response: HUD does not believe it is necessary to modify the proposed regulatory text as the commenter recommends. In § 5.100 of the proposed rule, HUD included a definition of "perceived gender identity" in order to differentiate between actual gender identity and perceived gender identity for purposes of this rule and the 2012 Equal Access Rule. Under that definition, perceived gender identity means the gender with which a person is perceived to identify based on that person's appearance, behavior, expression, other gender-related characteristics, or sex assigned to the individual at birth. In the final rule, the definition is amended to read as follows: Perceived gender identity means the gender with which a person is perceived to identify based on that person's appearance, behavior, expression, other gender-related characteristics, or sex assigned to the individual at birth or identified in documents. Because the definition of perceived gender identity included in the proposed rule and adopted by this rule includes gender expression, § 5.105(a)(2) of the rule addresses the commenter's concern that HUD-assisted or -insured housing shall be made available without regard to an individual's gender expression. HUD does not believe any revision to the text of § 5.105(a)(2) is necessary to address this concern. Any suggested amendment to Fair Housing Act regulations is outside the scope of this rulemaking.

Comment: Some commenters stated that the rule should create similar equal access to housing policies for transgender or gender nonconforming persons in all emergency shelters and facilities. Another commenter stated that the Fair Housing Act does not prohibit discrimination based on gender identity in shelters. A commenter stated that the lack of a law prohibiting discrimination against transgender persons in shelters has not stopped rescue missions and other shelter providers from meeting the diverse needs of transgender persons in crisis.

HUD Response: While HUD appreciates that commenters want to have this rule apply to all emergency shelters, the scope of this rulemaking is limited to shelters, other buildings and facilities, and programs funded in whole or in part by CPD. CPD is the HUD office that funds various types of shelters. While HUD believes that all emergency shelters, including those temporary, emergency shelters that are not subject to the requirements of the Fair Housing Act and that HUD does not fund, should provide equal access in accordance with an individual's gender identity, imposing those requirements on all emergency shelters is outside the scope of this rulemaking.

With respect to the commenter's statement about the Fair Housing Act, HUD seeks to clarify that, contrary to the commenter's stated view, the Fair Housing Act's prohibition of discrimination because of sex *does* include the prohibition of discrimination based on gender identity or nonconformance with gender stereotypes, which includes discrimination against an individual having a gender identity that does not conform to an individual's sex assigned at birth. While HUD disagrees with the commenter's broad statement that there is no law prohibiting discrimination based on gender identity in shelters, HUD agrees that it is beneficial for all shelters, including rescue missions, to continue to provide accommodation and services to transgender persons.

Comment: A commenter sought clarity regarding the application of the Fair Housing Act to shelters. The commenter asserted that the Fair Housing Act does not apply to homeless shelters because, in the commenter's view, they are not "dwellings" covered under the Fair Housing Act. The commenter stated that the term "dwelling" is not well-defined in case law, that emergency shelters are not dwellings under the Act; and that the prohibitions of section 3604 of the Fair Housing Act do not apply to "free" shelters and similar facilities because, in the commenter's view, such prohibitions only apply to housing that is for sale or rental. The commenter stated that, if HUD adopted a statement that the Fair Housing Act does not apply to homeless shelters, such adoption would "strengthen fair housing and mitigate confusion and misinterpretation among providers, fair-housing agencies, and shelter guests."

HUD Response: The commenter misunderstands HUD's statement about emergency shelters and the coverage of the Fair Housing Act. Contrary to the commenter's assertion, HUD does not categorically exclude temporary, emergency shelters providing short-term housing accommodations from coverage under the Fair Housing Act. In fact, HUD's established policy and regulations explicitly identify homeless shelters and other short-term or transient housing as "dwellings" subject to the Act.[13] The Act defines "dwelling" as "any building, structure, or portion thereof which is occupied as, or designed or intended for occupancy as, a residence by one or more families" and includes vacant land.[14] Thus, shelters generally are covered within the definition of dwelling, and many courts have held shelters and other short-term accommodations to be dwellings covered by the Fair Housing Act.[15] However, some shelters may not qualify as a "dwelling" under the Fair Housing Act, and, therefore, HUD has endorsed the following multiple factor analysis for determining whether a shelter is a covered dwelling for purposes of the Fair Housing Act: (1) Length of stay; (2) whether the rental rate for the unit will be calculated based on a daily, weekly, monthly, or yearly basis; (3) whether the terms and length of occupancy will be established through a lease or other written agreement; (4) what amenities will be included inside the unit, including kitchen facilities; (5) how the purpose of the property will be marketed to the public; (6) whether the resident possesses the right to return to the property; and (7) whether the resident has anywhere else to which to return.[16]

---

[11] *Macy* v. *Dept. of Justice,* No. 0120120821, 2012 EEOPUB LEXIS 1181, *13 (EEOC Apr. 20, 2012); *see also Lusardi* v. *Dept. of the Army,* No. 0120133395, 2015 EEOPUB LEXIS 896, *17 (EEOC Apr. 1, 2015).

[12] Attorney General Memorandum, Treatment of Transgender Employment Discrimination Claims Under Title VII of the Civil Rights Act of 1964 (Dec. 15, 2014), posted at *http://www.justice.gov/file/188671/download.* Similarly, the Office of Personnel Management revised its nondiscrimination regulations to make clear that sex discrimination under Title VII includes discrimination based on gender identity. *See, e.g.,* 5 CFR 300.102–300.103; *see also* OFCCP Directive 2014–02, Gender Identity and Sex Discrimination (Aug. 19, 2014) (stating that discrimination based on gender identity or transgender status is discrimination based on sex), posted at *http://www.dol.gov/ofccp/regs/compliance/directives/Directive_2014-02_508c.pdf.*

Determining whether a particular emergency shelter is a covered dwelling for purposes of the Fair Housing Act requires application of the multiple factors to its operation. No single factor is determinative. For instance, the absence of a rental fee or lease does not disqualify an accommodation from coverage under the Fair Housing Act.[17] Further, contrary to the commenter's view, section 3604 of the Fair Housing Act does not only apply to discriminatory conduct that involves a sale or rental. The Fair Housing Act has no such limitation. In addition to prohibitions against refusals "to sell or rent after making of a bona fide offer" and "to refuse to negotiate for the sale or rental," section 3604(a) also prohibits "otherwise mak[ing] unavailable or deny[ing]" a dwelling to any person protected under the Fair Housing Act.[18] HUD and courts have long made clear that a variety of conduct that does not involve sale or rental can make housing otherwise unavailable.[19] Similarly, section 3604(b) is not limited to conduct involving a sale or rental, as it also prohibits discrimination in the "provision of services or facilities in connection" with a dwelling.[20] HUD strongly disagrees that adopting a broad statement that the Fair Housing Act does not apply to homeless shelters would strengthen fair housing. HUD also emphasizes that this rule covers CPD-funded shelters and other buildings and facilities regardless of whether the facility qualifies as a dwelling under the Fair Housing Act.

Comment: Some commenters stated that the proposed rule is inconsistent with the Fair Housing Act, which forbids sex discrimination as to covered dwellings but not as to free, temporary, emergency shelters or other buildings or facilities, and which, therefore, evinces the intent of Congress to permit single-sex housing in the latter case. Commenters expressed concern that the decision by Congress to allow single-sex facilities that do not qualify as dwellings would be unenforceable if this rule is implemented as proposed; for example, if a women's shelter were required to admit a biological man based merely upon his assertion that he "identifies as" a woman, or if a men's shelter were required to admit a biological woman based merely upon her assertion that she "identifies as" a man.

HUD Response: As previously stated, the rule is not inconsistent with the Fair Housing Act. While the Fair Housing Act includes nondiscrimination requirements applicable to dwellings covered by the Act, it does not prohibit HUD from establishing additional program requirements through rulemaking. Temporary, emergency shelters and other buildings and facilities with physical limitations or configurations that require shared sleeping quarters or bathing facilities and that do not qualify as dwellings under the Fair Housing Act may operate single-sex shelters unless doing so would violate some other Federal, State, or local law. Under this rule, such shelters or other buildings and facilities funded by programs administered by CPD[21] must determine placement in such single-sex facilities in accordance with each applicant's or occupant's gender identity, regardless of sex assigned at birth or other factors. As noted in response to a prior comment, HUD's establishment of programmatic requirements for temporary, emergency shelters and other buildings and facilities funded through HUD programs is well within HUD's statutory authority and an important part of HUD's mission in ensuring access to housing for all Americans. Contrary to the public comment that suggests what Congress's intent was in creating single-sex facilities, HUD does not opine on Congress's intent behind permitting single-sex facilities, but does make clear in this rule that, for purposes of determining placement in a single-sex facility, placement should be made consistent with an individual's gender identity. This rule does not attempt to interpret or define sex.

Comment: One commenter expressed concern that Congress would see no need to enact the Equality Act, a bill that would expressly forbid discrimination in housing on the basis of sexual orientation and gender identity, once HUD issued a rule prohibiting such discrimination.

HUD Response: While HUD appreciates the commenter's desire to see Congress enact new legislation expanding antidiscrimination protections in housing, HUD does not believe the introduction of such legislation warrants delaying issuance of this important rule. Because many transgender persons are being denied access to temporary, emergency shelters and other building and facilities or are being placed and served in such shelters in accordance with their sex assigned at birth instead of in accordance with their gender identity, HUD believes it is necessary to issue this rule at this time to ensure that transgender and gender nonconforming persons are accorded equal access and are accommodated in accordance with their gender identity in programs, shelters, buildings, and facilities assisted by CPD. Given that this rulemaking applies only to providers that receive HUD funds and not more broadly, HUD does not believe that its rulemaking in this important area will impact any broader legislative action that Congress may choose to take.

---

[13] *See, e.g.,* Final Report of HUD Review of Model Building Codes, 65 FR 15740, 15746, 15747 (March 23, 2000) ("HUD specified as dwellings covered by the Act . . . such short-term housing as . . . homeless shelters."). *See also, e.g.,* 24 CFR 100.201 (the definition of "dwelling units" includes, *e.g.,* sleeping accommodations in shelters intended for occupancy as a residence for homeless persons); Supplement to Notice of Fair Housing Accessibility Guidelines: Questions and Answers about the Guidelines, 56 FR 9472, 9500 (March 6, 1991) (same); Implementation of the Fair Housing Amendments Act, 54 FR 3232, 3245 (January 23, 1989) (same).

[14] 42 U.S.C. 3602(b).

[15] See, *e.g., Schwartz* v. *City of Treasure Island,* 544 F.3d 1201, 1215 (11th Cir. 2008) (halfway houses for recovering addicts); *Lakeside Resort Enter.* v. *Bd. of Supervisors of Palmyra Twp.,* 455 F.3d 154, 158–60 (3rd Cir. 2006) (treatment facility); *Turning Point, Inc.* v. *City of Caldwell,* 74 F.3d 941, 942 (9th Cir. 1996) (homeless shelter); *Hovsons, Inc.* v. *Twp. of Brick,* 89 F.3d 1096, 1103 (3rd Cir. 1996) (nursing home); *U.S.* v. *Columbus Country Club,* 915 F.2d 877, 881 (3rd Cir. 1990) (summer bungalows); *Connecticut Hosp.* v. *City of New London,* 129 F. Supp. 2d 123, 135 (D. Conn. 2001) (halfway houses for substance abuse treatment); *Lauer Farms, Inc.* v. *Waushara County Board of Adjustment,* 986 F. Supp. 544, 557, 559 (E.D. Wis. 1997) (migrant farmworker housing); *Louisiana Acorn Fair Hous.* v. *Quarter House,* 952 F.Supp. 352, 359–60 (E.D. La. 1997) (time-share unit); *Woods* v. *Foster,* 884 F. Supp. 1169, 1175 (N.D. Ill. 1995) (homeless shelter); *Baxter* v. *City of Belleville,* 720 F. Supp. 720, 731 (S.D. Ill. 1989) (residence for terminally ill); *U.S.* v. *Hughes Mem'l Home,* 396 F. Supp. 544, 549 (W.D. Va. 1975) (home for needy children).

[16] *See* 65 FR at 15746.

[17] See, *e.g., Woods* v. *Foster,* 884 F. Supp. 1169, 1175 (N.D. Ill. 1995) (homeless shelter did not charge rent).

[18] 42 U.S.C. 3604(a).

[19] See, *e.g., Ojo* v. *Farmers Grp., Inc.,* 600 F.3d 1205, 1208 (9th Cir. 2010) (discriminatory pricing and denial of homeowners insurance violates 804(a) and (b)); *Nationwide Mut. Ins. Co.* v. *Cisneros,* 52 F.3d 1351, 1357–58 (6th Cir. 1995) (same); *Keith* v. *Volpe,* 858 F.2d 467, 482–484 (9th Cir. 1988) (municipal's refusal to permit low-income housing violates 804(a)). See also, *e.g.,* 24 CFR 100.70(d)(4) (refusing to provide municipal services or property or hazard insurance because of protected class).

[20] 42 U.S.C. 3604(b); see, *e.g.,* 24 CFR 100.65(b)(2) (failing or delaying maintenance because of protected class).

[21] HUD provided similar guidance to recipients and subrecipients that place eligible persons in single-sex temporary, emergency shelters or other facilities receiving ESG, CoC, or HOPWA funds. *See* Appropriate Placement for Transgender Persons in Single-Sex Emergency Shelters and Other Facilities, (Notice: CPD–15–02 (February 20, 2015)).

Comment: Commenters stated that the rule is not based on sufficiently exhaustive research and data, such as interviews with people not in the LGBT community, and only presents one-sided research on the issue of gender identity. A commenter said that while the rule notes that many transgender shelter-seekers would choose sleeping on the street rather than a shelter for their sex assigned at birth, HUD's rule does not address whether biological women would choose to sleep on the streets if their only other option were to share sleeping and bathing spaces with anatomically biological males who self-identify as women. Commenters stated that, before HUD institutes this rule, HUD needs more research on what risks placing males in female-only facilities will pose to women, and HUD should continue to search for solutions for providing safe services for particularly vulnerable males and, if vulnerable males must be placed at a women's shelter, female clients should be able to sleep, bathe, and use the toilet away from biological males.

HUD Response: As HUD program participants and the public are aware, HUD spent considerable time studying this issue. During the development of HUD's 2012 Equal Access Rule, commenters requested HUD to address the issue of temporary, emergency shelters that contain shared sleeping quarters and shared bathing facilities. HUD, however, declined to address that issue in the 2012 Equal Access Rule because of the need to conduct further research and examination of the issue. During the time since the 2012 Equal Access Rule was issued, HUD monitored and reviewed its own programs, national research, and other Federal agency policy to determine if transgender individuals had sufficient access to temporary, emergency shelters or if additional guidance or a national policy was warranted. HUD considered the issue not only from the perspective of transgender persons and other gender nonconforming persons, but also from the perspective of individuals whose sex assigned at birth and whose gender identity are the same. HUD has learned through its review that all individuals, including transgender persons and other gender nonconforming persons, can be safely accommodated in shelters and other buildings and facilities in accordance with their gender identity. Privacy concerns can be addressed through policy adjustments, such as the use of schedules that provide equal access to bathing facilities, and modifications to facilities, such as the use of privacy screens and, where feasible, the installation of single occupant restrooms and bathing facilities. Further, the 2016 Center for American Progress study cited in the Background section of this preamble revealed that shelters were willing to provide transgender women with appropriate shelter only 30 percent of the time. Given the 4-year examination of this issue prior to this rule and the recent evidence of continued and widespread practices that deny access or subject transgender individuals to unequal treatment, HUD is ready to address this matter in regulation and believes that this final rule sets the right approach.

Comment: Commenters stated that because the rule requires shelters and other programs and services to change their policies and procedures, oversight and accountability should be created or strengthened. Commenters stated that current lack of oversight within the shelter and emergency housing system threatens the lives of transgender, gender nonconforming, and intersex people; subjects them to violence and degradation without any accountability or protection; and violates their basic human rights and the equal protections that should be accorded them. Commenters stated that HUD should clarify, in the final rule or in another form, how HUD will monitor and enforce the CPD Equal Access Rule, including an amendment stating that without meaningful monitoring and enforcement as is done for protected groups under the Fair Housing Act, the promise of the rule may go unfulfilled. Other commenters stated that the system for filing complaints needs to be improved, and a complaint filing system needs to be incorporated at the local level, where marginalized transgender and gender nonconforming individuals seeking shelter have ready access to advocates who can assist them. A commenter stated that no organization should receive Federal funds without standing proof of compliance.

HUD Response: HUD agrees that safety, respectful treatment, and equal access are critical issues for transgender and gender nonconforming individuals, as they are for everyone, and HUD's regulations for the ESG program make it clear that all ESG-funded emergency shelters, including those with configurations that require shared sleeping quarters or shared bathing facilities, have had, and continue to have, a responsibility to create a safe environment for all occupants, particularly those of special populations (see 24 CFR 576.400(e)(3)(iii) for more information). Recipients, subrecipients, owners, operators, and managers of temporary, emergency shelters and other buildings and facilities and providers of services are expected to take the steps necessary to comply with this rule and maintain safe conditions for all shelter and facility residents and employees. When there is a threat to the safety of any resident, HUD expects recipients, subrecipients, and shelter or facility owners, operators, managers, and providers to take appropriate steps to address such threats. Such mitigating steps may include proactive measures to reduce risks such as increasing the shelter's security personnel, making adjustments to a facility's operating policies and schedules, and modifying shelter facilities to provide a single occupant bathing facility. HUD has heard from providers that adjusting a facility's operating policies and schedules is usually sufficient and does not cost additional funds, and thus HUD encourages agencies to start with this modification. HUD also notes that, for additional modifications that are necessary, some funded facilities, such as those under the ESG program, can use ESG funds to modify the shelter facility or provide additional security.

HUD believes that by requiring equal access for transgender individuals and other gender nonconforming persons in this regulation, HUD will be better able to monitor and enforce actions required to ensure equal access in temporary, emergency and other CPD-assisted buildings, facilities, and programs. Section 5.106(b) requires that recipients, subrecipients, operators, managers, and providers of temporary, emergency shelters, other buildings and facilities, programs, and services update their policies, if not already updated, to comply with providing equal access, which HUD can review when monitoring its recipients', subrecipients', and providers' compliance with the new requirements established by this final rule. In addition, § 5.106(d) requires that providers must document and maintain records of compliance with the requirements in § 5.106(b) of this rule for a period of 5 years.

Transgender and other gender nonconforming persons are encouraged to file complaints if they have been denied equal access to temporary, emergency shelters, other buildings and facilities, programs, or services in accordance with their gender identity. Individuals may file complaints of discrimination based on gender identity by calling 1–800–669–9777 (toll-free) or online at *http://portal.hud.gov/hudportal/HUD?src=/program_offices/fair_housing_equal_opp/online-complaint.* Persons who are deaf or hard of hearing or who have speech impairments may file a complaint via TTY by calling the Federal Relay Service at 1–800–877–8339 (toll-free).

Transgender and other gender nonconforming persons are encouraged to file complaints with HUD's CPD program office if they have been denied equal access to any services, accommodations, or benefits under CPD programs. Whenever a recipient (including subrecipients) of HUD funds fails or refuses to comply with program requirements, whether in statute or regulation, such failure or refusal shall constitute a violation of the requirements under the program in which the recipient is operating, and the recipient is subject to all sanctions and penalties for violation of program requirements, as provided for under the applicable program. Sanctions may include the withholding of HUD assistance. In addition, HUD may pursue an enforcement action when the Fair Housing Act is implicated. A housing provider who is found to have violated the Fair Housing Act may be liable for actual damages, injunctive and other equitable relief, civil penalties, and attorney's fees. As previously discussed, along with this rule, HUD is publishing in today's **Federal Register** for public comment a notice entitled "Equal Access Regardless of Sexual Orientation, Gender Identity, or Marital Status for HUD's Community Planning and Development Programs" that HUD proposes to require owners or operators of CPD-funded programs and facilities to post on bulletin boards and in other public spaces.

Comment: A commenter stated that the rule may place a significant burden upon the associational and religious liberty of beneficiaries and other stakeholders; for example, by requiring residents to share facilities with opposite-sex adults where their religions prohibit that.

HUD Response: The exclusion of an individual or family from CPD-funded shelter because the individual is transgender or the family has one or more transgender members is inconsistent with HUD's mission to ensure decent housing and a suitable living environment for all. It is equally inappropriate to isolate or ostracize individuals because their gender identity is not the same as their sex assigned at birth. It is incumbent on HUD to ensure that the regulations governing its housing programs make clear that such arbitrary exclusion, isolation, and ostracism will not be tolerated in HUD-assisted housing and shelters. Moreover, as noted in response to prior comments, in dwellings covered by the Fair Housing Act, exclusion or unequal treatment based on an individual's gender identity or nonconformance with gender stereotypes is discrimination because of sex and violates the Act. HUD would not tolerate denial of access, isolation, or ostracism on the basis of race, color, national origin, or disability relating to one shelter resident in order to accommodate the religious views of another shelter resident. The same is true with respect to the treatment of transgender and other gender nonconforming persons.

Faith-based organizations have long been involved in HUD's programs and provide many valuable services to low-income populations served by HUD. It is HUD's hope that faith-based organizations will continue to actively participate in HUD's CPD programs and provide services to transgender persons in accordance with the requirements set in this rule.

Comment: A commenter stated that the rule does not reflect the reality of providing shelter to people in challenging environments and with limited resources. Commenters stated that HUD should consider the following: (1) Providing additional resources to shelters to help them meet the privacy, health, and safety needs of clients; (2) examining what scope of client interview is permissible to enable staff to identify an attempted misuse of the proposed mandate without fear of legal challenge; (3) determining whether staff would be placed in an untenable position of pressure to accede to a request or demand contrary to their situational awareness and the reasonable concerns of other (often traumatized) shelter clients; (4) examining how a provider would gather timely and appropriate information that it believes is relevant to the actual situation but not necessarily a matter of health or safety; (5) determining whether the privacy concerns of other clients are legitimate criteria for placement; (6) examining how single-sex women shelter providers will reconcile differences between the Violence Against Women Act's (VAWA) "due consideration" approach for single-sex housing and the mandate in this rule, and how shelter providers will be expected to reconcile differences between the mandate of this regulation and the often conflicting regulations and guidance provided by other Federal, State and local housing agencies. A commenter said that the proposed rule will increase guesswork and the paperwork burden surrounding client placement and expressed concern about the legal repercussions to a provider for denying placement where there is a question as to "valid" gender identity.

HUD Response: HUD appreciates the items for consideration raised by the commenters and these were the very issues that HUD did, in fact, take into consideration before issuing this CPD Equal Access Rule, more than 4 years after the 2012 Equal Access Rule. In addition, before commencing this rulemaking, on February 20, 2015, CPD released Notice CPD–015–02, "Appropriate Placement for Transgender Persons in Single-Sex Emergency Shelters and Other Facilities," applicable to CPD's HOPWA, ESG, and CoC programs. This notice provides that HUD expects recipients, subrecipients, and providers to accommodate individuals in accordance with the individual's gender identity.[22] HUD has had over 1 year of experience with this guidance in place and such experience further informed HUD in development of the final rule. There is no reason to assume that transgender persons pose risks to health or safety. Indeed, experience under this guidance has shown that transgender and other gender nonconforming persons can be and have been safely accommodated in accordance with their gender identity in single-sex facilities without the types of disruptions feared by the commenter.

In response to the commenter's concern about the extent of questioning and investigation that shelter staff may perform prior to determining appropriate accommodations for transgender and other gender nonconforming persons, HUD has made modifications to the proposed rule at this final rule stage. Specifically, in § 5.106(b) of this final rule, HUD makes clear that it is inappropriate to subject individuals seeking accommodations to unnecessary, intrusive questioning about their gender identity or to ask them to provide anatomical information or documentary, physical, or medical evidence of their gender identity. Examples of unnecessary, intrusive questioning would be asking about surgeries, anatomy, and any other topics that are not necessary for placing and serving a client in the facility. Consistent with the approach taken by other Federal agencies, HUD has determined that the most appropriate way for shelter staff to determine an individual's gender identity for purposes of a placement decision is to rely on the individual's self-identification of gender identity. As for the comment about how to "reconcile differences between the VAWA's 'due consideration' approach to single-sex housing," HUD reviewed DOJ's guidance regarding the VAWA's nondiscrimination provision and does not see a conflict that needs to be reconciled.

---

[22] See notice at *https://www.hudexchange.info/resources/documents/Notice-CPD-15-02-Appropriate-Placement-for-Transgender-Persons-in-Single-Sex-Emergency-Shelters-and-Other-Facilities.pdf.*

HUD recognizes that emergency shelters are not the ideal placement for anyone, and that is why HUD is encouraging communities to move individuals and families into permanent housing as quickly as possible. In the meantime, HUD recognizes that there are security risks in operating shelters, but the obligation to provide for safety and security is not new, and the denial of equal access cannot be justified based on unfounded concerns about safety or security. Under this final rule, policies and procedures for CPD programs covered by this rule will have to include, if appropriate, provisions on nondiscriminatory measures to ensure the health, safety, security, and privacy of all occupants and staff in accordance with applicable Federal laws and regulations. Further, under this rule, recipients, subrecipients, owners, operators, managers, and providers of shelters and other buildings and facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities must take nondiscriminatory steps that may be necessary and appropriate to address privacy concerns raised by residents or occupants, and, as needed, update their admissions, occupancy, and operating policies and procedures. It would be appropriate for a recipient, subrecipient, owner, operator, manager, or provider to update its operating policies and procedures to reflect nondiscriminatory steps to address privacy concerns if providers repeatedly receive the same request from occupants that can be accommodated in the same manner. However, an update to their policies and procedures in order to address rare case-specific situations may not be necessary, although an exception to policies and procedures may be appropriate in such circumstances to avoid infringement on an individual's privacy concern. HUD believes that this final rule clarifies compliance and greatly reduces responsibility of the staff to determine gender identity for the purposes of placement.

Comment: A commenter stated that the proposed paperwork and record retention requirements of the proposed rule distract from the prime objective of shelters, disincentivizes participation in HUD programs, and make meeting the overarching objective of ensuring access to shelter for all more costly and burdensome.

HUD Response: This final rule eliminates most of the provisions of the proposed rule that required recordkeeping requirements, and as a result HUD has removed most of the recordkeeping requirements in this final rule. The only recordkeeping requirement that remains is the requirement to maintain records of policies and procedures to ensure that equal access is provided, and individuals are accommodated, in accordance with their gender identity. This requirement will aid HUD in monitoring compliance with this rule and taking enforcement action where needed.

Comment: Commenters expressed support for the rule's definitions of gender identity and perceived gender identity. A commenter said the original definition of gender identity encouraged discrimination by implying or directly giving providers the ability to determine gender through discriminatory perceptions based on gender stereotypes. A commenter stated that "transgender women are women and transgender men are men." Commenters stated that the rule's separation of definitions of actual and perceived gender identity will help to ensure that LGBT individuals receive equal access to shelter, for example, by clarifying concepts that may be unfamiliar to grant recipients.

HUD Response: HUD appreciates the commenter's support for the revised definition and agrees that it is important to differentiate between actual gender identity and perceived gender identity. As discussed earlier, the definition of "perceived gender identity" in this final rule includes a perception based on documents, to make clear that the identification of gender or sex on an individual's identity document may be different than a person's actual gender identity, and that the perceived gender identity of an individual based on information on the documents may not be the basis of discrimination against that individual.

Comment: Commenters stated that HUD's rule should allow persons to determine gender identity and expression free from harassment and violence, whether actual or perceived gender. Commenters stated that they appreciated that the definition of "perceived gender identity" covers discrimination based on gender expression, and they urged HUD to include consistent clarifying language to this effect in both the preamble to the final rule and in training and technical assistance for grantees.

HUD Response: As HUD noted in a prior response, by incorporating gender expression into the definition of perceived gender identity, the final rule requires recipients, subrecipients, and providers to make shelter available without regard to gender expression. HUD will take the commenter's recommendations into account when developing training and technical assistance materials.

Comment: Commenters stated their belief that self-reported gender identity should be afforded a lesser status than binary biological sex, because gender is subjective, mutable, and theoretical, whereas biological sex is objective, immutable, and demonstrable. Commenters stated that research demonstrates a lack of scientific consensus as to transgender status or that gender fluidity is a mental illness. Commenters stated that the rule contravenes the Constitution's recognition of a "fundamental, irreducible reproductive asymmetry" between women and men. Commenters stated that the rule should require the use of verifiable criteria, *e.g.,* medical history, to establish the authenticity of a self-identified transgender individual. A commenter stated that the rule puts "staff in the position of adjudicating who is a (transgender) woman and who is not," and that this is unfair to such staff and the populations they serve. A commenter stated that biological sex is relevant to decisions about single-sex housing and shared sleeping and bathing areas. Another commenter said HUD conflates the definitions of "sex," and "gender," and suggested that HUD define "sex" as the actual biological maleness or femaleness of a person and "gender" as the cultural sex-role, although the commenter stated that even this revision is still problematic because there are no universally agreed upon attributes for what constitutes particular roles.

Other commenters stated that sex is not "assigned" at birth, but is presented, observed, and recorded, and commenters recommended that the rule refer to the sex "presented" at birth rather than the sex "assigned" at birth. This commenter also supported the view that "perceived" gender identity is problematic, as perception varies from individual to individual, and asked how a provider is expected to perceive somebody else's identity. The commenter suggested that the rule state that perceived gender identity means the social sex-role the person is assumed to have an affinity for based on exhibited stereotyped behaviors commonly acknowledged to be associated with being either male or female and/or the actual biological sex of the person, but stated that there still needs to be some objective criteria for the definition to be of any real use, but using stereotyped behaviors in place of biological sex is problematic. A commenter said that the rule also does not define "transgender" or explain how a provider could distinguish between those who are sincere in their sex-role identity and those who are not. Further, the commenter said that because this rule enshrines expressions and characteristics as a legal sex category, it will negatively affect other laws concerning women's rights, and the definition of "woman" should be based on biological sex.

HUD Response: HUD appreciates and has considered the suggested revisions to the definition of "gender identity" offered by commenters. However, HUD declines to make the suggested changes at this final rule stage. As HUD observed in the 2012 Equal Access Rule, the number of suggested revisions to the definition of "gender identity" highlights a range of differing views among commenters regarding the meaning of this term. Consequently, HUD was required to determine which definition makes the most sense in this context. As noted earlier in this preamble, in the 2012 Equal Access Rule, HUD based its definition on the Matthew Shepard and James Byrd, Jr., Hate Crimes Prevention Act of 2009, on the basis that both this statute and HUD's policy sought to protect LGBT individuals. Subsequently, however, HUD evaluated its program recipient practices, reviewed research on discrimination of transgender individuals in shelter settings, solicited input on the experiences and concerns of both clients and providers, and reviewed its own guidance, as well as several other Federal agencies' gender-identity nondiscrimination policies. HUD found helpful, for instance, that the DOJ's guidance states that a program recipient "should ask a transgender beneficiary which group or service the beneficiary wishes to join," but may not "ask questions about the beneficiary's anatomy or medical history or make burdensome demands for identity documents." As noted in the proposed rule, HUD determined, in light of its review, that it would be more effective for the specific purpose of ensuring equal access to HUD programs to separate the definitions of actual and perceived gender identity and to require that any gender identity determinations in the context of CPD programs be based on an individual's self-identification. That does not mean that staff workers conducting intake procedures must account for perceived gender identity in determining placement. In fact, it means that staff workers must not use perceived gender identity and must only place an individual based on the individual's actual gender identity, without additional questions about anatomy, medical history, or identification documents. Transgender and gender nonconforming persons must not be placed based on perceived gender identity when it is in conflict with an individual's self-identified gender identity. This approach is consistent with current research, with HUD's existing guidance, and with other Federal agency policy. This approach does not require the provider to make any determination as to an individual's sincerity with respect to their gender.

In response to the comment with regard to this rule's impact on a "legal sex category," this rule does not provide a definition of "woman" or "sex." In this rule, HUD notes that gender identity—and whether a person identifies with their sex assigned at birth or not—is a component of sex. As such, HUD believes it was important to recognize the role of gender identity in its 2012 Equal Access Rule and to provide further guidance on how individuals are treated based on gender identity in this rule. In view of its role in ensuring access to housing for all Americans, HUD could not countenance denying equal access to shelter on the basis of gender identity, just as it could not countenance such treatment for characteristics such as race, color, national origin, or disability. As previously noted, HUD does not believe it is appropriate to isolate, ostracize, or treat people differently because of the way others, such as other shelter residents or shelter employees, view them.

Given the comments requesting guidance on the efforts a provider may use to identify an individual's gender identity, HUD revised the proposed rule, in this final rule, to provide clarity on this point. Specifically, HUD has included a provision in § 5.106(b) that makes clear that individuals may not be asked to answer intrusive questions, provide anatomical information, or provide documentary, physical, or medical evidence of the individual's gender identity. HUD notes that documents such as identification documents may list an individual's sex assigned at birth and not an individual's gender identity. Thus, an identification card or other document is not dispositive of an individual's gender identity. By including language that prohibits intrusive questioning or requests for anatomical information, documentation, or physical or medical evidence, HUD makes clear to providers, owners, operators, and managers that an individual's self-identification of gender identity is sufficient evidence of the individual's gender identity for purposes of making a decision regarding admission, placement, accommodation, placement, or services under this final rule. While documentation of gender identity may not be required for purposes of establishing an individual's gender identity or determining eligibility for a program, HUD recognizes that an individual may need to provide documentation of identity in order to apply for certain types of assistance, such as healthcare, Social Security benefits, or employment. In instances where the provider receives documentation and that documentation states a different gender marker than was identified by the individual as their gender identity, the provider must continue to serve the individual in accordance with their self-identified gender identity.

As previously stated, it is not uncommon for transgender persons to have identification documents that indicate the individual's sex assigned at birth instead of the individual's gender identity, so identity documents should not be viewed as evidence contesting an individual's self-identification of gender identity.

Comment: A commenter stated that the rule recognizes that some people do not identify as either male or female and that such persons must be permitted to choose which option is most consistent with their gender when accessing single-sex shelters or other buildings or facilities or services. Commenters asked HUD to clarify how the rule applies to people who identify in nonbinary, gender-fluid, intersex, or gender nonconforming terms. Commenters stated that nonbinary individuals constitute a vulnerable subgroup within the transgender population, particularly because their identity may be less familiar to program staff, but they are nevertheless entitled to the same acceptance and respect for their gender identities as are others. A commenter said the medical community has widely recognized the importance of recognizing gender identities other than male or female, or nonbinary genders, and providing those with nonbinary genders equal access to services. Commenters stated that an individual whose gender identity is neither male nor female should have the right to state which program or facility is most consistent with their identity and asked HUD to include language to this effect in the preamble to the final rule. The commenters also asked HUD to discuss in its training and technical assistance for grantees the rule's application to persons who are gender nonconforming or who do not identify as male or female, in training and technical assistance for grantees. Commenters stated that the rule should expressly state that refusing service or access to individuals who are gender nonconforming or who do not identify as either male or female violates the proposed rule. Commenters stated that when only male or female accommodations are available, equal access requires that persons who do not identify as either male or female must be permitted to determine which option is most consistent with their gender identity. A commenter stated that HUD should amend its forms and databases to permit individuals to identify as something other than male or female and to instruct program staff that individuals must be permitted to self-identify their own gender. Another commenter said that the rule does not mention intersex persons or persons with a difference of sexual development (DSD) and, consistent with current trends in case law, coverage of the rule should be expanded to include persons with intersex conditions and DSD.

Another commenter said that while it understands that the proposed regulations are requiring nonbinary users to choose between facilities for the two majority genders, the commenter believes that, over the long term, single-sex systems are going to have to become integrated if they are to cost-effectively serve an expanding variety of gender identities. This commenter asked HUD to start conceptualizing a new system that can comfortably accommodate nonbinary users. A commenter said HUD should encourage recipients to undertake the following: The development and creation of all-gender spaces; the creation of policies, practices, and staffing structures that would allow programs and facilities to be safely designated as all-gender; and the creation of practices and facility upgrades that afford all residents increased personal privacy.

HUD Response: HUD appreciates the comments regarding individuals who do not identify as either male or female and individuals who are nonbinary, gender-fluid, intersex, or gender nonconforming. While HUD did not reference each of these groups in its proposed rule or the regulatory text of this final rule, HUD's use of terminology is not intended to exclude people because of the words they use to describe themselves. HUD recognizes that there is more work to do in this area to ensure that, to the greatest extent possible, all individuals are treated equally and appropriately accommodated in HUD-funded programs, shelters, services, and other facilities. In circumstances where an individual does not identify as male or female and such information is relevant to placement and accommodation, the individual should be asked the gender with which the individual most closely identifies. In these circumstances, the individual is in the best position to specify the more appropriate gender-based placement as well as the placement that is most likely to be the safest for the individual—either placement with males or placement with females.

While HUD appreciates the suggestions about future actions it may take to better accommodate everyone in shelters, HUD declines to address these comments in detail as these issues are beyond the scope of this rulemaking. HUD will consider these issues for future rulemaking. As the commenters suggest, HUD will also consider training and guidance for shelter providers, operators, and managers on best practices for dealing with individuals who do not identify as male or female and individuals who are nonbinary, intersex, or gender nonconforming. HUD agrees that individuals in these groups may be particularly vulnerable, and that training and technical assistance may be helpful in addressing the needs of these populations of shelter residents.

Comment: A commenter stated that HUD should not follow the approach taken by DOJ in implementation of the Prison Rape Elimination Act because DOJ regulations included provisions allowing correctional agencies broad discretion to make "case-by-case" decisions regarding whether placement in a male or female facility would ensure the individual's health and safety. The commenter stated that while DOJ explained in its rule's preamble that "an agency may not simply assign the inmate to a facility based on genital status," few, if any, State agencies are complying with this provision, with the result that agencies are maintaining their prior practices of automatically placing individuals exclusively based on their genital anatomy, even when nominally adopting policy language that mirrors the Federal rule. The commenter stated that such discretion is not appropriate or permissible under regulations implementing Federal nondiscrimination requirements. Another commenter stated that the most essential element of a successful nondiscrimination policy is the basic rule that housing must be based on a person's self-identified gender, not on their sex assigned at birth. A commenter stated that placement should not be conditioned on whether a transgender person has undergone any medical treatment or been able to change the gender markers on their identification documents, or have to look a certain way. Another commenter stated, citing several examples in the United States and elsewhere, that shelters that have adopted a rule basing gender on self-identification, as opposed to sex assigned at birth, report uniform success in being able to serve and integrate transgender people into their programs and services.

HUD Response: HUD has never intended to give broad discretion to recipients and providers to make case-by-case decisions. The proposed rule required providers of temporary, emergency shelter and services to document the specific facts, circumstances, and reasoning relied upon in any case-by-case determination that results in an alternative admission, accommodation, benefit, or service to an individual or their family.

To clarify that placement is to be made on the basis of an individual's self-identification of gender, § 5.106(b) of this final rule includes a provision stating that individuals may not be subjected to intrusive questioning relating to their gender identity or asked to provide anatomical information, documentation, or physical or medical evidence of gender identity. Therefore, this final rule makes clear that placement in accordance with an individual's gender identity cannot be conditioned on whether a transgender person has undergone medical treatment, has been able to change identification documents to reflect their gender identity, or has a certain appearance or gender expression.

Additionally, as discussed earlier in this preamble, in § 5.106(c) of this final rule, which addresses placement and accommodation in temporary, emergency shelters and other facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities, HUD removes the proposed rule language that, under narrow circumstances, a written case-by-case determination could be made on whether an alternative accommodation for a transgender individual would be necessary to ensure health and safety. In its place, HUD provides that placement and accommodation of individuals in shelters and other buildings and facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities shall be made in accordance with an individual's gender identity. Further, this revised paragraph (c) provides for post-admission accommodations, where, after an individual has been admitted to a shelter or other building and facilities, providers must take nondiscriminatory steps that may be necessary and appropriate to address privacy concerns raised by residents or occupants. This provision for post-admission accommodations applies to all individuals, regardless of gender identity.

Comment: In contrast to the preceding comment, commenters stated that the requirements that an accommodation be permitted only in "narrow" or "rare" circumstances, and then only when "necessary" to ensure two specified interests—health and safety— is too circumscribed to adequately protect the interests of all residents. The commenter stated that an accommodation that furthers the interests in protecting the health and safety of residents should be allowed, for example, even if not, strictly speaking, "necessary," and not only at the request of the person "claiming" to be transgender. Commenters stated that, even as to housing facilities that admit both men and women, residents should not be required to share with persons of the opposite sex those areas, such as sleeping and bathing areas, properly reserved to persons of one sex, for reasons of privacy.

HUD Response: As discussed above, this final rule notes that providers need to take nondiscriminatory steps that may be necessary and appropriate to address privacy concerns raised by residents or occupants. HUD stresses the use of the term "nondiscriminatory" in this provision. An example of a nondiscriminatory step to address privacy concerns would be accommodating a request of a domestic violence victim who has specific privacy concerns to bathe at specific, separate times from other shelter or facility occupants.

As HUD has noted, it has studied the issue for 4 years and determined, following the lead of other Federal agencies, that to ensure equal access, the general rule must be that individuals are accommodated in accordance with their gender identity. If HUD were to provide broader discretion, placement decisions would rely on more subjective factors that might differ from provider to provider based on the views, beliefs, and unsubstantiated fears of individual shelter staff.

Comment: A commenter said the rule prohibits a determination from being based on complaints of other shelter residents when those complaints are based on actual or perceived gender identity, but HUD should provide guidelines to help providers distinguish complaints that are based on recognition of threat because of a client's biological sex, as opposed to "gender identity."

HUD Response: HUD agrees that the language referenced by the commenter could cause confusion. HUD, therefore, has removed the language and makes clear that in temporary, emergency shelters and other buildings and facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities, placements and accommodations shall be made in accordance with an individual's gender identity. Once an individual is accommodated, providers shall take appropriate steps to address privacy concerns raised by all residents and occupants. By considering complaints, and taking appropriate action in response, a provider will minimize the risk of harassment occurring among occupants and between staff and occupants.[23] Such actions must, however, be nondiscriminatory.

Comment: Commenters stated that the rule should clarify that shelters may give transgender people case-by-case alternative or modified accommodations only when they request them and not at the mandate of shelter staff and/or to accommodate the wishes, fears, or discomfort of others—and that such alternatives or modifications shall not be based on a person's actual or perceived gender identity. Commenters also stated that the rule should clarify that shelters shall provide accommodations requested by a transgender shelter-seeker, and only when those accommodations are reasonable and appropriate to protect the health, safety or privacy of that individual. Commenters stated that a person's ability to request an alternative or modified placement should not be limited to "shared sleeping quarters or shared bathing facilities" and recommended that the provision for such accommodations be incorporated into paragraph (b) of § 5.106 (which is titled Equal Access in accordance with gender identity) rather than in separate paragraph (d) of § 5.106 (which is titled Referrals). A commenter said that many shelters find that, where possible, providing increased privacy for all residents is ideal; for example, private rooms and bathrooms and showers with locks. A commenter stated that the rule should mandate that shelters provide unisex bathrooms with individual showers.

Commenters stated that the rule should clarify that any alternative or modified placements must provide access to the same or substantially equivalent services, or a "comparable alternative program." Commenters stated that HUD should clarify that shelters will be in noncompliance with the rule if they provide some services (*e.g.,* hotel vouchers) but otherwise deny equivalent services, such as the same length of stay, other supportive services offered by the shelter, or services provided at the primary program site due to a lack of transportation. A commenter stated that a provider that refers an individual to another program should be required to confirm that the individual received shelter or services at that alternative program.

HUD Response: As previously discussed, this final rule removes the case-by-case determination language in the proposed rule and establishes that individuals in HUD-funded shelters and other buildings and facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities must be accommodated in accordance with their gender identity. This final rule makes clear that providers do not have the discretion to suggest that individuals may not be accommodated in shelters that match their gender identity because their gender identity differs from their sex assigned at birth. As a result, HUD has eliminated the referral provision that was in § 5.106 (d) of the proposed rule. Section 5.106(b) of this final rule broadly discusses how policies and procedures must ensure equal access to CPD programs based on gender identity.

---

[23] Unlawful harassment in shelters that qualify as dwellings violates the Fair Housing Act. See Quid Pro Quo and Hostile Environment Harassment and Liability for Discriminatory Housing Practices Under the Fair Housing Act, proposed rule, 80 FR 63720 (Oct. 21, 2015).

As discussed earlier in this preamble, the revisions to this final rule do not preclude the existing possibility that any occupant may request a referral to an alternate project or that, in such cases, staff may provide a referral to another project or, where none is available and funding permits, offer clients a hotel or motel voucher. HUD appreciates the commenters' concerns that a transgender individual who is provided an alternative accommodation at the individual's request should be provided an accommodation that is comparable to the shelter within which the individual originally sought accommodation and agrees that when providers make referrals they should ensure that an opportunity to access equivalent alternative accommodations, benefits, and services is provided, or the requestor should receive a referral to a comparable alternative program with availability and equivalent accommodations, benefits, and services.

HUD is encouraged that many shelters are providing increased privacy for all residents, such as private rooms and bathrooms and showers with locks, and as discussed earlier in this preamble, HUD encourages this where feasible. This rule, however, does not mandate this configuration. Mandatory configuration of shelters is beyond the scope of this rulemaking.

Comment: Other commenters stated that they oppose any exception to the requirement that shelter be provided based on gender identity to protect the health and safety of shelter employees or other people staying in the shelter, because such an exception is not necessary and will be used as pretext to deny shelter to transgender individuals. Commenters stated that under the proposed rule language, it is not clear whose health and safety the exception is intended to protect. A commenter stated that the very allowance of an exception reinforces the attitude that a person is a threat to others based solely on her or his status as a transgender individual. The commenter stated that if a shelter provider is concerned that a transgender individual's behavior or conduct poses a threat to others' health or safety, then the provider can and should address that in the same way that it addresses the problematic conduct of any other person staying in the shelter.

Another commenter stated that the exception, which is ambiguous, should be removed, because it is unclear from the preamble what kind of "health and safety" circumstances would (or should) ever justify denying shelter to a transgender individual in accordance with their gender identity. A commenter stated that the exception should apply only to the health and safety of the shelter seeker, meaning that only shelter seekers could make these requests for other accommodations for themselves. Other commenters stated that HUD should take special care to ensure that providers are not choosing these alternatives in order to circumvent the general prohibition on discrimination. A commenter stated that it would be very helpful for HUD to provide guidance in the form of specific examples of effective policy adjustments, as well as other ways shelter and housing providers can mitigate actual or perceived threats to health or safety, in a less burdensome way. A commenter stated that guidance is needed to address what covered providers should do in scenarios where they lack financial resources to provide alternative accommodations or referrals, so as not to violate the rule.

HUD Response: HUD appreciates these comments and, as discussed previously, HUD has revised the rule to clarify that placement and accommodation must be made in accordance with an individual's gender identity.

Comment: A commenter stated that the goals of this rule could conflict with the goals of "Violence Against Women Reauthorization Act of 2013: Implementation in HUD Housing Programs," a rule that seeks to offer expanded protections to victims of domestic violence, dating violence, sexual assault, and stalking within HUD-assisted and HUD-insured housing. The commenter suggested that HUD provide additional guidance to operating facilities with shared sleeping quarters on how to offer alternative accommodations to transgender individuals when there are residents that are sensitive to sharing facilities with the opposite sex due to their experiences with domestic violence.

HUD Response: HUD's proposed rule implementing the housing protections of VAWA, which as the commenter noted would expand protections to victims of domestic violence, dating violence, sexual assault, and stalking in HUD-assisted and HUD-insured housing, does not conflict with this final rule. HUD's proposed rule on VAWA would implement statutory requirements that: (1) Prohibit housing providers under certain HUD programs (covered housing providers) from denying or terminating assistance or occupancy rights to individuals because they are or have been victims of domestic violence, dating violence, sexual assault, or stalking; (2) require covered housing providers to notify tenants and applicants of their rights under VAWA, and detail what documentation covered housing providers may ask for; (3) require covered housing providers to create emergency transfer plans; and (4) provide for lease bifurcations. Nothing in HUD's rule proposing to implement VAWA contradicts this rulemaking requiring that individuals be housed and receive services in accordance with their gender identity.

Further, as HUD explained in the CPD Equal Access proposed rule, VAWA imposed a new grant condition that prohibits discrimination by recipients of grants administered by DOJ, including grants to provide housing assistance for survivors of domestic violence. Although this provision relates to DOJ, and not to HUD, HUD noted that on April 9, 2014, DOJ's published guidance entitled "Frequently Asked Questions: Nondiscrimination Grant Condition in the Violence Against Women Reauthorization Act of 2013," which addresses how a recipient of DOJ funds can operate a single-sex facility funded through VAWA and not discriminate on the basis of gender identity. The DOJ guidance states that recipients that operate sex-segregated or sex-specific programs should assign a beneficiary to the group or service that corresponds to the gender with which the beneficiary identifies, and may consider on a case-by-case basis whether a particular housing assignment would ensure the victim's health and safety, but recipients may not make a determination about services for one beneficiary based on the complaints of another beneficiary when those complaints are based on gender identity. The guidance further states that, for the purpose of assigning a beneficiary to sex-segregated or sex-specific services, best practices dictate that the recipient should ask a transgender beneficiary which group or service the beneficiary wishes to join, but the recipient may not ask questions about the beneficiary's anatomy or medical history or make burdensome demands for identity documents.

HUD's rule requires that individuals be accommodated in accordance with their gender identity. It is beyond the scope of this rule to detail methods for best serving victims of domestic violence, dating violence, sexual assault, or stalking. However, as discussed earlier, this final rule requires that providers must take nondiscriminatory steps that may be necessary and appropriate to address privacy concerns raised by all residents or occupants. HUD notes that both victims and perpetrators of domestic violence and other VAWA crimes include persons who are transgender or gender nonconforming individuals and persons who are not.

Comment: Commenters asked that HUD include other CPD programs that will be active in the near future, including the Housing Trust Fund and the Rural Housing Stability Assistance program, or provide an indicator that the list is nonexhaustive so the Secretary can add more CPD programs.

HUD Response: HUD's intent was to cover all CPD programs, as noted in the preamble to the proposed rule. Therefore, HUD makes clear in § 5.106(a) that additional CPD programs, such as the Housing Trust Fund and Rural Housing Stability Assistance programs, are included.

Comment: Commenters stated that the rule should clarify that transgender persons have a right to housing and treatment consistent with their gender identity in all circumstances—in the preamble and training and technical assistance. Other commenters said it is essential that the rule address more directly the problem of violence, including the high rates of sexual assault, against LGBT and gender nonconforming persons in federally funded shelters.

HUD Response: HUD's 2012 Equal Access Rule and this CPD Equal Access Rule explicitly acknowledge the higher rate of discrimination and acts of violence experienced by transgender persons and both rules address the issue that transgender individuals and other gender nonconforming persons must be able to participate in HUD programs on an equal basis as all other program participants. HUD guidance and training on its Equal Access rules cover these subjects.

Comment: The rule must address public and staff perceptions.

HUD Response: The final rule makes clear that transgender and other gender nonconforming individuals are to be admitted, placed, accommodated, and provided with services in accordance with their gender identity. Public and staff perceptions are not an appropriate basis for denial or limitation of access. Any additional rulemaking to address public and staff perceptions of transgender and gender nonconforming persons is beyond the scope of this rulemaking. HUD acknowledges, however, that such topics may be appropriate for training and technical assistance materials for shelter providers.

Comment: Commenters stated that HUD-funded programs should be required to create and implement written policies specifying how they will combat harassment, violence, and sexual assault and, in particular, how they will protect the health and safety of LGBT and gender nonconforming persons and others who are at increased risk of sexual violence. A commenter recommended that HUD require its recipients and subrecipients to create written policy and guidelines combating violence against persons marginalized due to their sexual orientation or gender identity and to require data collection to help monitor accountability. Commenters stated that HUD should provide guidance detailing necessary provisions of such policies and recommended best practices, for example, guidance or best practices pertaining to the shelter-seeker's own individualized safety assessment, through training and technical assistance for grantees. Commenters also stated that HUD should specify that the failure to create and implement such policies could result in noncompliance with the regulations and, thereby, jeopardize Federal funding and/or result in HUD taking action under its regulations. Another commenter stated that it is unclear who has the responsibility to establish and amend policies and procedures under the rule, so HUD should clarify that the covered recipients, subrecipients, owners, operators, managers, and providers must create, implement, and revise these policies and procedures as necessary. The commenter stated that HUD should identify in a subsequent notice the specific types of individuals and entities that have these duties within each housing program. The commenter also stated that HUD should provide sample policies and procedures, especially regarding privacy and security, so that covered individuals or entities that are unfamiliar with gender identity issues can have access to models in devising their own policies and procedures.

Commenters stated that the rule should mandate training for shelter staff as a prerequisite to receiving HUD funding. Another commenter stated that guidance from advocacy organizations suggests that ongoing resident training should be implemented in addition to current HUD-required staff training. A commenter stated that HUD should ensure that community organizations are made aware of the rule, once the rule is implemented, in order to better support their outreach work to transgender and gender nonconforming people in poverty.

Other commenters asked HUD to provide training on the requirement that recipients and subrecipients must treat transgender individuals respectfully by using an individual's self-identified name and pronouns, regardless of whether they have been able to legally change it.

HUD Response: HUD agrees with the commenters that successful implementation of this rule depends in no small part on guidance and training. HUD undertook intensive training efforts following publication of its 2012 Equal Access Rule and 2015 Notice CPD–15–02, and HUD intends to do the same for this CPD Equal Access Rule. With respect to commenters' questions about the establishment of policies, § 5.106(b) of this final rule (and of the proposed rule) requires that the admissions, occupancy, and operating policies and procedures of recipients, subrecipients, owners, operators, managers, and providers (covered by this rule), including policies and procedures to protect privacy, health, safety, and security, shall be established or amended, as necessary, and administered in a nondiscriminatory manner so: (1) Equal access to programs, shelters and other buildings and facilities, benefits, services, and accommodations is provided to an individual in accordance with the individual's gender identity, and in a manner that affords equal access to the individual's family; (2) an individual is placed, served, and accommodated in accordance with the individual's gender identity; (3) an individual is not subjected to intrusive questioning or asked to provide anatomical information or documentary, physical, or medical evidence of the individual's gender identity; and (4) consistent with § 5.105(a)(2),eligibility determinations are made and assisted housing is made available in CPD programs without regard to actual or perceived gender identity.

Comment: A commenter stated that the rule's case-by-case analysis, training, and referral requirements will involve more time and resources than HUD estimates. The commenter stated that HUD should provide additional resources and tools to program grantees so that proper training can be conducted, particularly for small grantees with limited resources.

HUD Response: As discussed earlier, this final rule eliminates the provision regarding a case-by-case analysis. As HUD noted in response to the preceding comment, HUD will undertake training and provide training and guidance to assist recipients and subrecipients under the CPD programs covered by this rule.

Comment: Commenters stated that they support the elimination of the inquiries prohibition provision for the following reasons: (1) The prohibition would likely cause confusion in the context of applying § 5.106, as it may be construed to prohibit any discussion of gender identity and (2) it appears to prohibit the routine and voluntary collection of demographic data regarding sexual orientation and gender identity for purposes of program evaluation—and, while an inquiry regarding sexual orientation or gender identity may constitute discrimination or be evidence of discrimination under the rule, inquiries for legitimate and nondiscriminatory purposes should be permitted. Commenters stated that they supported the removal of the prohibition to the extent that the final rule is clear that shelter and housing providers can only inquire about an applicant's or resident's sexual orientation and gender identity for lawful purposes; for example, to determine unit size and as part of the routine and voluntary collection of demographic data concerning sexual orientation and gender identity for program evaluation, so long as the data is collected and used for nondiscriminatory purposes in a nondiscriminatory fashion. A commenter stated, in support of removing the prohibition, and providing suggested language, that they urged HUD to require that specific protocols be put in place to protect the confidentiality of information about sexual orientation or transgender status.

HUD Response: HUD is committed to ensuring the safety and privacy of all individuals, including transgender and gender nonconforming individuals, in CPD programs. In the proposed rule, HUD expressed its intent in proposing the removal of the inquiries prohibition. HUD emphasized that it would only permit recipients or subrecipients to inquire about a person's sexual orientation or gender identity for lawful, nondiscriminatory purposes. In the final rule, to prohibit inappropriate inquiries related to gender identity, HUD included language in § 5.106(b) stating that it would be inappropriate to subject individuals to intrusive questioning or ask them to provide anatomical information or documentary, physical, or medical evidence of the individual's gender identity. In addition, as noted previously in this preamble, CPD previously issued guidance, "Appropriate Placement for Transgender Persons in Single-Sex Emergency Shelters and Other Facilities" (Notice CPD–15–02, Feb. 20, 2015), which outlines best practices for appropriate and inappropriate inquiries related to sex and provides guidance, and recommends staff training, on addressing safety or privacy concerns. HUD intends to issue further guidance in connection with the issuance of this final rule.

Comment: A commenter stated, citing recommended guidance and model policies, that Massachusetts prohibits gender-based inquiries only in cases where shelter guests are perceived as transgender, suggesting that implementation of the proposed rule would be possible without removing the prohibition.

HUD Response: As noted in HUD's proposed rule, removal of the inquiries prohibition would allow temporary, emergency shelters and other facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities to ask the individual's gender identity, and it would permit inquiries of the individual's gender identity and sexual orientation to determine the number of bedrooms to which a household is entitled. This is an inquiry that could be asked of all individuals, and not solely of those who are perceived to be transgender. Further, as HUD has stated, removal of the inquiries prohibition also reaffirms that HUD permits mechanisms for voluntary and anonymous reporting of sexual orientation or gender identity for compliance with data collection requirements of State and local governments or Federal assistance programs.

Comment: Commenters stated that the rule should expressly prohibit program staff from asking individuals questions about their anatomy, medical procedures, or medical history or making requests for identity documents or other documentation of gender as a precondition for being housed consistent with their gender identity.

HUD Response: Although the final rule removes the provision of § 5.105 that prohibited inquiries into an individual's sexual orientation or gender identity for purposes of facilitating providers' compliance with the requirement of § 5.106 that an individual is to be admitted, placed, accommodated, and provided services in accordance with the individual's gender identity, HUD agrees with commenters that transgender and gender nonconforming individuals should not be required to answer invasive questions about their anatomy or medical history in order to be accommodated and provided services in CPD programs. To address this concern, HUD has revised § 5.106(b) to prohibit intrusive questions related to gender identity and prohibit requests for anatomical information and requests for documentary, physical, or medical evidence.

Comment: Commenters recommend that HUD emphasize in the preamble, and in training and technical assistance, the importance of protecting the privacy of information related to a shelter seeker's sexual orientation and gender identity. A commenter stated that transgender people in particular face serious risks of danger, including verbal harassment and physical assault, when their transgender status or gender identity is revealed without their consent. The commenter said that steps to keep a shelter seeker's sexual orientation and/or gender identity confidential include, without limitation: (1) Safeguarding all documents and electronic files, (2) containing this information and having conversations about these topics in private to prevent disclosure, (3) establishing explicit nondiscrimination provisions, (4) ensuring safe environments in programs and shelters, (5) implementing rigorous confidentiality safeguards, and (6) ensuring that shelter staff members receive appropriate training. The commenter said that successful implementation of these important requirements will facilitate the collection of much needed data, allowing HUD to better determine the populations its programs serve, their needs and consumer experiences, and their use of programs and facilities.

HUD Response: Many of CPD's programs that govern temporary, emergency shelters and other buildings and facilities impose strict confidentiality requirements to ensure the privacy of individuals that are housed in these facilities. (See §§ 574.440, 576.500(x), 578.103(b) and (d)(2), and 578.23(c)(4)(i).) This final rule requires that privacy be considered in adopting admissions, occupancy, and operating policies and procedures in § 5.106(b) and provides that shelters and other buildings and facilities take nondiscriminatory steps that may be necessary and appropriate to address privacy concerns raised by residents or occupants in § 5.106(c). Further guidance will address privacy and confidentiality in data collection.

Comment: Commenters stated that HUD should clarify in the preamble to the final rule, and in training and technical assistance to its field staff, that inquiries that are used to limit the provision of shelters or housing, to harass an individual, or to further any other discriminatory purpose fall under the prohibition on discrimination. Commenters stated that, by contrast, HUD should state clearly in those areas that the routine and voluntary collection of demographic information from all clients or program participants is permissible, so long as it is collected and used in a nondiscriminatory fashion.

HUD Response: HUD appreciates the commenters raising this issue and will address this issue in guidance. HUD reiterates that conduct that violates the rule may also violate the Fair Housing Act if the facility is subject to the Fair Housing Act's nondiscrimination requirements and the conduct is because of race, color, religion, national origin, familial status, sex, or disability.

IV. Findings and Certifications

Regulatory Review—Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made on whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. A determination was made that this final rule is a "significant regulatory action" as defined in section 3(f) of Executive Order 12866 (although not economically significant, as provided in section 3(f)(1) of that order).

This final rule is consistent with Administration policy in its direction that providers in all CPD programs must ensure that their policies and procedures to protect privacy, health, safety, and security are administered so that equal access is provided to HUD programs in accordance with an individual's gender identity. This final rule also clarifies how temporary, emergency shelters and other buildings and facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities comply with the requirement that equal access be provided to programs, buildings, facilities, services, benefits, and accommodations in accordance with an individual's gender identity. This clarification will benefit clients accessing CPD-funded programs, including those with temporary, emergency shelters and other buildings and facilities, by assuring that all clients receive equal access and will benefit the CPD-funded facilities by making compliance with HUD's equal access requirements easier.

These requirements benefit all occupants by ensuring that providers understand that they need to be responsive to individual health, safety, security, and privacy concerns, while ensuring that they do not take any discriminatory steps to address these concerns. This final rule also amends the definition of gender identity and sexual orientation in § 5.100 to clarify the difference between actual and perceived gender identity, which is necessary to the adoption of § 5.106, and to reflect recent changes in the definition of sexual orientation that uses updated terminology but does not expand the coverage of the term. This final rule eliminates the prohibition on inquiries relating to sexual orientation or gender identity in § 5.105(a)(2)(ii). Both of these changes make it easier for recipients and subrecipients of CPD funding, as well as owners, operators, and managers of shelters, buildings, and other facilities, and providers of services funded by CPD programs to comply with the requirements of both §§ 5.105(a)(2)(i) and 5.106.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Approximately 4,000 providers participating in the CPD programs covered by this rule are small organizations, but the rules requirement that organizations maintain records will be limited. Organizations are already required to maintain up-to-date policies and procedures in accordance with HUD guidance and regulations. The only change is that all CPD programs must now maintain records of prior policies and procedures for up to 5 years from when they make changes to comply with these requirements. HUD believes that these limited recordkeeping requirements on small organizations are reasonable to ensure equal access to CPD programs, facilities, services, benefits, and accommodations in accordance with an individual's gender identity. Accordingly, for the foregoing reasons, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number. The information collection requirements for the CPD programs impacted by this rule—HOME, CDBG (State and entitlement), HOPWA, ESG, and CoC—have been approved by OMB and assigned OMB control numbers 2506–0171, 2506–0085, 2506–0077, 2506–0133, 2506–0089, and 2506–0199. The information collection requirements for CPD's Housing Trust Fund and Rural Housing Stability Assistance programs will be included when those programs are implemented.

Environmental Impact

This rule sets forth nondiscrimination standards. Accordingly, under 24 CFR 50.19(c)(3), this rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either: (i) imposes substantial direct compliance costs on State and local governments and is not required by statute or (ii) preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This rule does not have federalism implications and would not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and on the private sector. This rule does not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

List of Subjects in 24 CFR Part 5

Administrative practice and procedure, Aged, Claims, Drug abuse, Drug traffic control, Grant programs—housing and community development, Grant programs—Indians, Individuals with disabilities, Loan programs—housing and community development, Low and moderate income housing, Mortgage insurance, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated in the preamble, and in accordance with HUD's authority in 42 U.S.C. 3535(d), HUD amends 24 CFR part 5 as follows.

PART 5—GENERAL HUD PROGRAM REQUIREMENTS; WAIVERS

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437d, 1437f, 1437n, 3535(d), Sec. 327, Pub. L. 109–115, 119 Stat. 2936, and Sec. 607, Pub. L. 109–162, 119 Stat. 3051.

■ 2. In § 5.100, revise the definitions for "Gender identity" and "Sexual orientation" to read as follows:

§ 5.100 Definitions.

* * * * *

Gender identity means the gender with which a person identifies, regardless of the sex assigned to that person at birth and regardless of the person's perceived gender identity. Perceived gender identity means the gender with which a person is perceived to identify based on that person's appearance, behavior, expression, other gender related characteristics, or sex assigned to the individual at birth or identified in documents.

* * * * *

Sexual orientation means one's emotional or physical attraction to the same and/or opposite sex (*e.g.*, homosexuality, heterosexuality, or bisexuality).

* * * * *

§ 5.105 [Amended]

■ 3. In § 5.105, remove paragraph (a)(2)(ii) and the paragraph (a)(2)(i) heading and redesignate paragraph (a)(2)(i) as (a)(2).

■ 4. Add § 5.106 to read as follows:

§ 5.106 Equal access in accordance with the individual's gender identity in community planning and development programs.

(a) *Applicability.* This section applies to assistance provided under Community Planning and Development (CPD) programs, including assistance under the following CPD programs: HOME Investment Partnerships program (24 CFR part 92), Housing Trust Fund program (24 CFR part 93), Community Development Block Grant program (24 CFR part 570), Housing Opportunities for Persons With AIDS program (24 CFR part 574), Emergency Solutions Grants program (24 CFR part 576), Continuum of Care program (24 CFR part 578), or Rural Housing Stability Assistance Program (24 CFR part 579). The requirements of this section apply to recipients and subrecipients, as well as to owners, operators, and managers of shelters and other buildings and facilities and providers of services funded in whole or in part by any CPD program.

(b) *Equal access in accordance with gender identity.* The admissions, occupancy, and operating policies and procedures of recipients, subrecipients, owners, operators, managers, and providers identified in paragraph (a) of this section, including policies and procedures to protect privacy, health, safety, and security, shall be established or amended, as necessary, and administered in a nondiscriminatory manner to ensure that:

(1) Equal access to CPD programs, shelters, other buildings and facilities, benefits, services, and accommodations is provided to an individual in accordance with the individual's gender identity, and in a manner that affords equal access to the individual's family;

(2) An individual is placed, served, and accommodated in accordance with the gender identity of the individual;

(3) An individual is not subjected to intrusive questioning or asked to provide anatomical information or documentary, physical, or medical evidence of the individual's gender identity; and

(4) Eligibility determinations are made and assisted housing is made available in CPD programs as required by § 5.105(a)(2).

(c) *Placement and accommodation in temporary, emergency shelters and other buildings and facilities with shared sleeping quarters or shared bathing facilities*—(1) *Placement and accommodation.* Placement and accommodation of an individual in temporary, emergency shelters and other buildings and facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or shared bathing facilities shall be made in accordance with the individual's gender identity.

(2) *Post-admission accommodations.* A recipient, subrecipient, owner, operator, manager, or provider must take nondiscriminatory steps that may be necessary and appropriate to address privacy concerns raised by residents or occupants and, as needed, update its admissions, occupancy, and operating policies and procedures in accordance with paragraph (b) of this section.

(d) *Documentation and record retention.* Providers shall document and maintain records of compliance with the requirements in paragraph (b) of this section for a period of 5 years.

Dated: September 14, 2016.

Julián Castro,

Secretary.

[FR Doc. 2016–22589 Filed 9–20–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE880

Fisheries of the Exclusive Economic Zone Off Alaska; Exchange of Flatfish in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is exchanging unused flathead sole and rock sole Community Development Quota (CDQ) for yellowfin sole CDQ acceptable biological catch (ABC) reserves in the Bering Sea and Aleutian Islands management area. This action is necessary to allow the 2016 total allowable catch of yellowfin sole in the Bering Sea and Aleutian Islands management area to be harvested.

DATES: Effective September 21, 2016 through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands management area (BSAI) according to the Fishery Management Plan for Groundfish of the Bering Sea and

Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2016 flathead sole, rock sole, and yellowfin sole CDQ reserves specified in the BSAI are 1,832 metric tons (mt), 5,460 mt, and 16,473 mt as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016) and following revision (81 FR 63716, September 16, 2016). The 2016 flathead sole, rock sole, and yellowfin sole CDQ ABC reserves are 5,257 mt, 11,778 mt, and 6,179 mt as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016) and following revision (81 FR 63716, September 16, 2016).

The Coastal Villages Regional Fund has requested that NMFS exchange 215 mt of flathead sole and 245 mt of rock sole CDQ reserves for 460 mt of yellowfin sole CDQ ABC reserves under § 679.31(d). Therefore, in accordance with § 679.31(d), NMFS exchanges 215 mt of flathead sole, 245 mt of rock sole CDQ reserves for 460 mt of yellowfin sole CDQ ABC reserves in the BSAI. This action also decreases and increases the TACs and CDQ ABC reserves by the corresponding amounts. Tables 11 and 13 of the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016), and following revision (81 FR 63716, September 16, 2016), are revised as follows:

TABLE 11—FINAL 2016 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH, AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

Sector	Pacific ocean perch			Flathead sole	Rock sole	Yellowfin sole
	Eastern aleutian district	Central aleutian district	Western aleutian district	BSAI	BSAI	BSAI
TAC	7,900	7,000	9,000	16,470	55,180	150,450
CDQ	845	749	963	1,617	5,215	16,933
ICA	200	75	10	5,000	6,000	3,500
BSAI trawl limited access	685	618	161	0	0	14,979
Amendment 80	6,169	5,558	7,866	9,853	43,965	115,038
Alaska Groundfish Cooperative	3,271	2,947	4,171	1,411	11,129	43,748
Alaska Seafood Cooperative	2,898	2,611	3,695	8,442	32,836	71,290

Note: Sector apportionments may not total precisely due to rounding.

TABLE 13—FINAL 2016 AND 2017 ABC SURPLUS, COMMUNITY DEVELOPMENT QUOTA (CDQ) ABC RESERVES, AND AMENDMENT 80 ABC RESERVES IN THE BSAI FOR FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE

[Amounts are in metric tons]

Sector	2016 Flathead sole	2016 Rock sole	2016 Yellowfin sole	2017 Flathead sole	2017 Rock sole	2017 Yellowfin sole
ABC	66,250	161,100	211,700	64,580	145,000	203,500
TAC	16,470	55,180	150,450	21,000	57,100	144,000
ABC surplus	49,780	105,920	61,250	43,580	87,900	59,500
ABC reserve	49,780	105,920	61,250	43,580	87,900	59,500
CDQ ABC reserve	5,472	12,023	5,719	4,663	9,405	6,367
Amendment 80 ABC reserve	44,308	93,897	55,531	38,917	78,495	53,134
Alaska Groundfish Cooperative for 2016[1]	4,145	22,974	24,019	n/a	n/a	n/a
Alaska Seafood Cooperative for 2016[1]	40,163	70,923	31,512	n/a	n/a	n/a

[1] The 2017 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the flatfish exchange by the Coastal Villages Regional Fund in the BSAI. Since these fisheries are currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 8, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 16, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–22694 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150818742–6210–02]

RIN 0648–XE894

Fisheries of the Exclusive Economic Zone Off Alaska; Shortraker Rockfish in the Western Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of shortraker rockfish in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary because the 2016 total allowable catch of shortraker rockfish in the Western Regulatory Area of the GOA will be reached.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), September 19, 2016, through 2400 hours, A.l.t., December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2016 total allowable catch (TAC) of shortraker rockfish in the Western Regulatory Area of the GOA is 38 metric tons (mt) as established by the final 2016 and 2017 harvest specifications for groundfish of the GOA (81 FR 14740, March 18, 2016).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2016 TAC of shortraker rockfish in the Western Regulatory Area of the GOA will be reached. Therefore, NMFS is requiring that shortraker rockfish in the Western Regulatory Area of the GOA be treated as prohibited species in accordance with § 679.21(b).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay prohibiting the retention of shortraker rockfish in the Western Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 15, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and § 679.21 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 16, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–22724 Filed 9–16–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 183
Wednesday, September 21, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 923

[Doc. No. AMS–SC–16–0077; SC16–923–1 PR]

Cherries Grown in Designated Counties in Washington; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Washington Cherry Marketing Committee (Committee) to increase the assessment rate established for the 2016–2017 and subsequent fiscal periods from $0.15 to $0.25 per ton of Washington cherries handled. The Committee locally administers the marketing order and is comprised of growers and handlers of cherries operating within the production area. Assessments upon cherry handlers are used by the Committee to fund reasonable and necessary expenses of the marketing order. The fiscal period begins April 1 and ends March 31. The assessment rate would remain in effect indefinitely unless modified, suspended or terminated.

DATES: Comments must be received by October 6, 2016.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or internet: *http://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Teresa Hutchinson or Gary D. Olson, Northwest Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724, Fax: (503) 326–7440, or Email: *Teresa.Hutchinson@ams.usda.gov* or *GaryD.Olson@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This proposed rule is issued under Marketing Order No. 923, as amended (7 CFR part 923), regulating the handling of cherries grown in designated counties in Washington, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 12866, 13563, and 13175.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the order now in effect, Washington cherry handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate, as proposed herein, would be applicable to all assessable Washington cherries beginning April 1, 2016, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule would increase the assessment rate for the 2016–2017 and subsequent fiscal periods from $0.15 to $0.25 per ton of Washington cherries.

The order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are growers and handlers of Washington cherries. They are familiar with the Committee's needs, and with the costs for goods and services in their local area, and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2013–2014 and subsequent fiscal periods, the Committee recommended, and the USDA approved, an assessment rate of $0.15 per ton of Washington cherries that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on May 18, 2016, and unanimously recommended expenditures of $57,150 for the 2016–2017 fiscal period. In comparison, the previous fiscal period's budgeted expenditures were $59,750. The Committee also unanimously recommended an assessment rate of $0.25 per ton of Washington cherries. The recommended assessment rate of $0.25 is $0.10 higher than the rate currently in effect.

The expenditures recommended by the Committee for the 2016–2017 fiscal period include $25,000 for the management fee; $7,000 for compliance; $5,000 for the data management fee; $5,000 for accounting administration; $5,000 for research; $4,000 for Committee travel; $3,000 for an audit; and $3,150 for miscellaneous other expenses. In comparison, expenditures for the 2015–2016 fiscal period were $25,000 for the management fee; $7,000 for compliance; $5,000 for the data management fee; $7,000 for accounting administration; $5,000 for research; $4,000 for Committee travel; $4,000 for an audit; and $2,750 for miscellaneous other expenses.

Committee members estimated the 2016 fresh cherry production to be approximately 150,000 tons, which would be less than the 2015 production of 165,358 tons by 15,358 tons. However, cherry production tends to fluctuate due to the effects of weather, pollination, and tree health. The Committee's recommended assessment rate was derived by dividing the 2016–2017 anticipated expenses by the expected shipments of Washington cherries, while also taking into account the Committee's monetary reserve. The recommended assessment rate of $0.25 per ton, when multiplied by the 150,000 tons of estimated 2016 Washington cherry shipments, is expected to generate $37,500 in handler assessments. The projected revenue from handler assessments, together with funds from the Committee's monetary reserve, would be adequate to cover the 2016–2017 budgeted expenses of $57,150. The Committee expects its monetary reserve to decrease from $49,661 at the beginning of the 2016–2017 fiscal period to approximately $30,011 at the end of the 2016–2017 fiscal period. That amount would be within the provisions of the order and would provide the Committee with greater ability to absorb fluctuations in assessment income and expenses into the future.

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee would continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of the Committee meetings are available from the Committee and USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 2016–2017 budget and those for subsequent fiscal periods would be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are 53 handlers of Washington sweet cherries subject to regulation under the order and approximately 1,500 growers in the regulated production area. Small agricultural service firms are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than $7,500,000, and small agricultural growers are defined as those having annual receipts of less than $750,000.

National Agricultural Statistics Service has prepared a preliminary report for the 2015 shipping season showing that prices for the 171,600 tons of sweet cherries that entered the fresh market averaged $2,380 per ton. Based on the number of growers in the production area (1,500), the average grower revenue from the sale of sweet cherries in 2015 can therefore be estimated at approximately $272,272 per year. In addition, the Committee reports that most of the industry's 53 handlers reported gross receipts of less than $7,500,000 from the sale of fresh sweet cherries last fiscal period. Thus, the majority of growers and handlers of Washington sweet cherries may be classified as small entities.

This proposal would increase the assessment rate collected from handlers, for the 2016–2017 and subsequent fiscal periods from $0.15 to $0.25 per ton of Washington cherries handled. The Committee unanimously recommended 2016–2017 expenditures of $57,150 and an assessment rate of $0.25 per ton. The proposed assessment rate of $0.25 is $0.10 higher than the rate established for the 2013–2014 fiscal period.

The 2016–2017 Washington cherry crop is estimated at 150,000 tons. At the proposed $0.25 per ton assessment rate, the Committee anticipates that assessment income of approximately $37,500, along with reserve funds, would be adequate to cover budgeted expenses for the 2016–2017 fiscal period. With the proposed assessment rate and budgeted expense level, the Committee anticipates that $19,650 would need to be deducted from the monetary reserve. As such, reserve funds are estimated to be at $30,011 on March 31, 2017. That reserve level is within the maximum permitted by the order of approximately one fiscal period's operational expenses (§ 923.42(a)(2)).

The expenditures recommended by the Committee for the 2016–2017 fiscal period include $25,000 for the management fee; $7,000 for compliance; $5,000 for the data management fee; $5,000 for accounting administration; $5,000 for research; $4,000 for Committee travel; $3,000 for the audit; and $3,150 for miscellaneous other expenses.

In comparison, expenditures for the 2015–2016 fiscal period were $25,000 for the management fee; $7,000 for compliance; $5,000 for the data management fee; $7,000 for accounting administration; $5,000 for research; $4,000 for Committee travel; $4,000 for the audit; and $2,750 for miscellaneous other expenses.

The Committee discussed alternatives to this action, including recommending alternative expenditure levels and assessment rates. Although lower assessment rates were considered, none were selected because they would not have generated sufficient income to administer the order.

A review of historical data and preliminary information pertaining to the upcoming fiscal period indicates that the grower price for the 2016–2017 fiscal period could average $2,380 per ton of sweet cherries. Therefore, the estimated assessment revenue for the 2016–2017 fiscal period, as a percentage of total grower revenue, is approximately 0.01 percent.

This action would increase the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs may be passed on to growers. However, these costs would be offset by the benefits derived by the operation of the order.

In addition, the Committee's meeting was widely publicized throughout the Washington cherry industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the May 18, 2016, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0189. No changes in those requirements are necessary as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large Washington cherry handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this action.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 15-day comment period is provided to allow interested persons to respond to this proposed rule. Fifteen days is deemed appropriate because: (1) The 2016–2017 fiscal period began on April 1, 2016, and the order requires that the assessment rate for each fiscal period apply to all assessable Washington cherries handled during such fiscal period; (2) the Committee needs to have sufficient funds to pay its expenses, which are incurred on a continuous basis; (3) handlers are already shipping Washington cherries from the 2016 crop; and (4) handlers are aware of this action, which was unanimously recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years.

List of Subjects in 7 CFR Part 923

Cherries, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 923 is proposed to be amended as follows:

PART 923—CHERRIES GROWN IN DESIGNATED COUNTIES IN WASHINGTON

■ 1. The authority citation for 7 CFR part 923 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 923.236 is revised to read as follows:

§ 923.236 Assessment rate.

On and after April 1, 2016, an assessment rate of $0.25 per ton is established for the Washington Cherry Marketing Committee.

Dated: September 16, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–22740 Filed 9–20–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF COMMERCE

Economic Development Administration

13 CFR Part 311

[Docket No.: 150826785–5785–01]

RIN 0610–AA67

Innovative Technologies in Manufacturing Loan Guarantee Program

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice of proposed rulemaking; request for public comment.

SUMMARY: Through this notice of proposed rulemaking ("NPRM"), the Economic Development Administration ("EDA," or "the Agency"), U.S. Department of Commerce ("DOC"), proposes and requests comments on the Agency's implementation of section 26 of the Stevenson-Wydler Technology Innovation Act of 1980 (the "Stevenson-Wydler Act"), enacted as part of the America COMPETES Reauthorization Act of 2010 ("COMPETES Act"). The Stevenson-Wydler Act authorizes EDA to provide loan guarantees for obligations to small- and medium-sized manufacturers for the use or production of innovative technologies. These guarantees will enable innovative technology manufacturers to obtain capital otherwise unavailable to them.

DATES: Written comments on this NPRM must be received by EDA's Office of the Chief Counsel no later than 5 p.m. eastern time on December 20, 2016.

ADDRESSES: Comments on the NPRM may be submitted through any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. EDA will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).
- *Agency Web site: http://www.eda.gov/.* EDA has created an online feature for submitting comments. Follow the instructions at *http://www.eda.gov/.*
- *Mail:* Economic Development Administration, Office of the Chief Counsel, U.S. Department of Commerce, 1401 Constitution Avenue NW., Suite 72023, Washington, DC 20230. Please indicate "Comments on EDA's regulations" and Docket No. 150826785–5785–01 on the envelope.

All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible.

FOR FURTHER INFORMATION CONTACT: Rachel A. Wallace, Attorney-Advisor, Office of the Chief Counsel, Economic Development Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Suite 72023, Washington, DC 20230; telephone: (202) 482–5443.

SUPPLEMENTARY INFORMATION:

Background

Established under the Public Works and Economic Development Act of 1965, as amended (42 U.S.C. 3121 *et seq.*) ("PWEDA"), EDA's mission is to lead the Federal economic development agenda by promoting innovation and competitiveness, preparing American regions for growth and success in the worldwide economy. EDA makes investments in and provides technical assistance to economically distressed communities in order to facilitate job creation for U.S. workers, increase private sector investment, promote American innovation, and accelerate long-term sustainable economic growth. EDA's regulations, codified at 13 CFR parts 301 through 315, provide the framework through which the Agency administers its economic development assistance programs.

As part of the COMPETES Act enacted on January 4, 2011, section 26 of the Stevenson-Wydler Act (15 U.S.C. 3721) authorized the Secretary of Commerce "to establish a program to provide loan guarantees for obligations to small- or medium-sized manufacturers for the use or production of innovative technologies." 15 U.S.C. 3721(a). In general, the Federal loan "guarantee" represents the portion of the loan that the Federal agency will repay to the lender if the borrower defaults on its loan payments. *See* 15 U.S.C. 3721(s)(4) (definition of "Loan Guarantee"); and 3721(d) ("A loan guarantee shall not exceed an amount equal to 80 percent of the obligation . . .").

As required by the Stevenson-Wydler Act, a "loan guarantee may be made under the program only for a project that re-equips, expands, or establishes a manufacturing facility in the United States—(1) to use an innovative technology or an innovative process in manufacturing; (2) to manufacture an innovative technology product or an integral component of such a product; or (3) to commercialize an innovative product, process, or idea that was developed by research funded in whole or in part by a grant from the Federal government." 15 U.S.C. 3721(b). The Stevenson-Wydler Act defines an "innovative technology" as "a technology that is significantly improved as compared to the technology in general use in the commercial marketplace in the United States at the time the loan guarantee is issued." 15 U.S.C. 3721(s)(3). Similarly, the term "innovative process" is defined as "a process that is significantly improved as compared to the process in general use in the commercial marketplace in the United States at the time the loan guarantee is issued." 15 U.S.C. 3721(s)(2).

The Secretary of Commerce has delegated the responsibility of implementing and administering the Innovative Technologies in Manufacturing ("ITM") Program, which includes promulgating regulations as required by the Stevenson-Wydler Act (see 13 U.S.C. 3721(l)), to EDA. EDA was appropriated the following amounts for the ITM Program: In fiscal year 2012, up to $5 million; in both of the fiscal years 2013 and 2014, $5 million; and in fiscal year 2015, $4 million. These amounts are "to remain available until expended," for section 26 loan guarantees "to subsidize total loan principal, any part of which is to be guaranteed, not to exceed $70,000,000." See Public Law 112–55 (FY12); Public Law 113–6 (FY13); Public Law 113–76 (FY14); Public Law 113–235 (FY15). Put another way, from FY12–FY15, EDA received a total of $14 million and up to $19 million in no-year, appropriated funds to support a maximum of $280 million in loans that would be subject to EDA's guarantee.

Although EDA administered business loan programs in the past, it has been more than 30 years since the Agency has been actively engaged in the process of loan making. In 1965, Title II of PWEDA (former 42 U.S.C. 3121–3246) authorized EDA to make direct loans and guarantee loans to businesses willing to establish and expand operations in economically distressed areas for the purpose of developing land and facilities for industrial or commercial use. In addition, under the Trade Act of 1974 (former 19 U.S.C. 2341–2374), businesses adversely affected by foreign imports could apply for EDA direct loans and loan guarantees. However, by the mid-1980s EDA had essentially stopped making direct loans and guaranteeing new loans under PWEDA. Similarly, EDA stopped administering loans under the Trade Act when the International Trade Administration's Office of Trade Assistance was created in 1982. Four years later, Congress rescinded the DOC's authority to make Trade Adjustment Assistance loans and loan guarantees in the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99–272). EDA's authority under PWEDA for making direct loans and loan guarantees was not eliminated until the enactment of the Economic Development Administration and Appalachian Regional Development Act of 1998 (Pub. L. 105–393) which reauthorized EDA's programs for the first time since 1982.

Given the loss of institutional knowledge over the years, the need to leverage existing staff resources and the unique requirements of the ITM Program, EDA adopted a multi-pronged approach to Program implementation. Seeking to gauge market demand and obtain input about how to structure the Program from the public and stakeholders, on April 17, 2013, EDA published a "Request for Comments on Developing a Program To Provide Loan Guarantees to Small- or Medium-Sized Manufacturers" in the **Federal Register** (78 FR 22801). EDA received four comments, none from lenders. In general, the commenters noted that similar Federal programs already existed that were not being fully utilized and for the ITM Program to succeed, it needed to be easily accessible.

At the same time, EDA sought out the expertise and experience of two Federal agencies with well-established business loan programs—the SBA (*e.g.,* 7(a) loan guarantee program) and the Department of Energy (*e.g.,* 1703 Program). Meeting with representatives of these agencies and closely examining the structure of another loan program (the Department of Agriculture's Business & Industry (B&I) Program), provided EDA with invaluable guidance and insight into best practices for standing up a loan guarantee program, including the development of program elements such as borrower eligibility standards and lender oversight, creation of program documents such as forms and operating manuals as well as administrative components such as staffing and electronic loan processing/servicing.

In 2014, EDA hired a full-time attorney and procured a contractor with extensive Federal loan program expertise to support the Agency's implementation efforts. Equipped with the information gathered from its due diligence and the subsequent analysis, EDA modeled the structure of the ITM Program closely after SBA's 7(a) loan guarantee program (hereinafter, referred to as "SBA's 7(a) program"). Similar to SBA's 7(a) program, the ITM Program is designed to help certain creditworthy businesses—specifically, small and medium-sized manufacturers—acquire financing when they cannot otherwise obtain credit at reasonable terms. EDA, like SBA in the 7(a) context, will not make loans itself. Instead, EDA will guarantee a portion of the loan made by a participating lending institution. Thus, taxpayer funds are only paid out in the event of borrower default. This process reduces the risk to the lender (incentivizing the lender to make the loan), but not to the borrower, who remains obligated for the full debt, even in the event of default. The similarities in the two programs, as well as the significant differences attributable to EDA's own statutory requirements and policy priorities, are reflected in EDA's proposed regulatory framework, which is summarized below. EDA seeks public input through this NPRM on the proposed regulatory framework. In particular EDA seeks comment on:

- The biggest impediments to small or medium-sized manufacturers receiving a loan from a lending institution.
- Whether the EDA's ITM loan program would make it more likely for lenders to lend to manufacturers, especially small or medium-sized manufacturers.
- What lending institutions should require for a borrower to demonstrate that a market exists for an innovative technology product.
- Whether there is an existing market for small to medium-sized business loans in the innovative manufacturing sector that are not currently being met.
- What other requirements in a loan guarantee program would be necessary for a lender to offer such loans.
- The manufacturing size threshold and definition to be considered a medium-sized manufacturer.
- The typical loan size that a small-medium business in innovative manufacturing would apply for.
- Whether securing a loan through the EDA ITM program to support the use or production of innovative technologies would assist manufacturers with access to outside capital.
- Other activities and outcomes from the EDA ITM loan program that would best support innovation in the manufacturing sector.

EDA also seeks comment on the proposed regulatory text, which is summarized below.

Subpart A—General Provisions

Subpart A serves as the foundation of the ITM Program regulations, defining key terms and outlining core programmatic elements. For example, it includes borrower eligibility criteria, types of ineligible businesses, and permissible uses of loan proceeds by borrowers. In addition, lender ethical standards, creditworthiness criteria, additional loan requirements involving personal guarantees, collateral, and bonding are explained. It should be noted that the basic eligibility criteria for both Borrowers and Lenders are similar to SBA's, but have been modified to reflect the statutory requirements and program specific goals of the ITM Program, including the requirement that the applicant borrower be prospectively or currently engaged in an Innovative Technological Project. For the same reasons, eligible uses of ITM Program loan proceeds are different in key respects from SBA's 7(a) program. One notable difference is that unlike SBA, EDA will not permit loan proceeds to be used for working capital. Some of the more significant terms defined in this subpart are highlighted below:

(1) *Associate:* An associate is a person or entity with a close connection to an ITM Program lender or borrower, with this legal relationship established if specific criteria are met (*e.g.,* an associate of a lender includes an officer, director, or holder of at least a 5 percent interest of the value of the lender's stock or debt instruments, or an agent involved in the loan process). As set forth in these regulations, the existence of an associate will have ramifications for the lender or borrower, such as affecting a borrower's size for eligibility purposes and having an associate's activities imputed to the lender for conflict of interest purposes.

(2) *Innovative Technological Project:* This term captures the requirement in Stevenson-Wydler that a loan guarantee can only be used to finance certain types of projects, emphasizing that the project must be "innovative," and "Technological in nature," produce certain products or processes (*e.g.,* a "significantly improved product or process") and result in one of four required actions (*e.g.,* "utilizing this innovative technology in the process of manufacturing an existing product").

(3) *Lender:* Eligible lenders have been defined as lenders that are in good standing under the SBA Preferred Lenders Program (PLP). Under this program, SBA delegates the final credit decision and most servicing and liquidation authority and responsibility to carefully selected lenders. Lenders are considered for PLP status based on their record with SBA, and must have demonstrated a proficiency in processing and servicing SBA-guaranteed loans. EDA will require lenders to certify that they are in good standing under the PLP at the time a loan application is submitted. Failure by a lender to certify to its status under the PLP will be grounds for denial of its participation in the ITM Program. If it is determined that a lender is not in good standing at the time of certification or at any point after a loan guarantee is approved for that lender, EDA may deny liability on that loan guarantee.

(4) *Manufacturing:* Manufacturing includes those activities associated with the relevant six-digit manufacturing NAICS codes (311111–333999).

(5) *Medium-sized Business:* A medium-sized business is defined relative to SBA's definition of a small business; namely, a business that has a maximum size that is twice the maximum size of a small business using the same six-digit NAICS code and same measurement standards as the calculation for a small business.

(6) *Small Business:* If a business is "small" under SBA's size standards, the business will likewise be considered a small business for purposes of the ITM Program.

Subpart B—Requirements Imposed Under Other Laws and Orders

Subpart B discusses various laws and orders applicable to borrowers, lenders and the use of ITM Program loan proceeds. Specifically, flood insurance requirements, child support obligation compliance, flood-plain and wetlands management, lead-based paint requirements, earthquake hazard management, and coastal barrier island restrictions are addressed. In addition, this subpart emphasizes that compliance with all other generally applicable laws such as environmental, civil rights and anti-discrimination laws, is required.

Subpart C—Applicability and Enforceability of Loan Program Requirements

Subpart C details the nature of a lender's obligation to comply with the ITM Program requirements. Further, it emphasizes that, because of the status of lenders and borrowers as independent entities, EDA is not liable for any injury suffered as a result of a lender's or borrower's wrong-doing with respect to a loan.

Subpart D—Loan Applications

Closely mirroring SBA's 7(a) program regulations and process, subpart D describes the application process for an ITM Program loan, including the required contents of a loan application. In addition, this subpart discusses how lenders and applicants are notified of approval or denial of an application, as well as the procedures involved when a lender is seeking reconsideration of EDA's decision to reject an application.

Subpart E—Reporting

Subpart E outlines lender reporting requirements. In addition, it affirms the applicant's duty to disclose any fees paid to agents assisting the applicant in obtaining the loan as well as the obligation of lenders, borrowers and EDA employees to notify the DOC Inspector General of any suspected fraud regarding an ITM Program loan.

Subpart F—Limitations on Use of Proceeds

To prevent a potential loss-shift to EDA from an existing borrower obligation, subpart F prohibits a borrower's use of loan proceeds to refinance unsecured or under-secured loans.

Subpart G—Maturities; Interest Rates; Loan and Guarantee Amounts

Subpart G delineates the key parameters for loan guarantees made under the ITM Program, including the statutory maximum percentage of a loan eligible for a guarantee, which is 80 percent. The ITM Program regulations impose a loan size limit of $10 million or, if written approval is obtained from EDA, $15 million. This subpart also addresses loan maturities, providing that the term of a loan shall be the lesser of 30 years or 90% of the projected useful life of the financed physical asset. In addition, while covering fixed interest rate loans, this subpart provides that a lender may use a variable rate of interest, upon EDA approval after the lender's satisfaction of certain conditions with respect to the base rate, changes to the rate, amount of fluctuation from the base rate, maximum spreads and amortization.

Subpart H—Fees

Subpart H discusses fees that can be properly charged under the ITM Program. These regulatory provisions authorize EDA to charge lenders a guarantee fee as well as a monthly servicing fee. Note that the guarantee fee may be increased if the guaranteed portion of the loan increases. Also discussed in this subpart are the fees that a lender is permitted to charge the borrower, which includes the guarantee fee after the first disbursement as well as service and late payment fees.

Subpart I—Participation Criteria

Subpart I discusses requirements for a lender's initial and continued eligibility for participation in the ITM Program. At the outset, this subpart makes clear that EDA may enter into an authorization with a lender to make ITM program loans, which may include terms to allow for the patents and technology needed for the Innovative Technological Project to be available to complete and operate the Innovative Technological Project for any borrower, including EDA pursuant to its rights of subrogation. Among other requirements, the lender must be in good standing under the SBA Preferred Lenders Program at all times and must maintain its ability to evaluate, process, close, disburse, service, liquidate, and litigate loans in its portfolio. One notable difference between the ITM Program and SBA's 7(a) program is that EDA does not allow a lender to securitize or otherwise sell or transfer an ITM Program loan without prior approval from EDA and the execution of a separate securitization agreement with EDA.

Subpart J—Loan Modifications and Servicing Actions

Subpart J underscores that a lender may defer payments on a loan and can extend the maturity of a loan only with the prior written consent of EDA. With respect to loan modifications, this subpart addresses standards to which lenders must adhere (*e.g.,* commercially reasonable manner consistent with prudent lending standards) when engaging in loan servicing, liquidation, and debt collection litigation activities. In addition, those servicing and liquidation actions that require the prior written consent of EDA (*e.g.,* compromise of the loan principal balance; accelerating the maturity of the note) are listed.

Subpart K—EDA Purchase of Guaranteed Portion

Subpart K applies when a lender requests that EDA honor its guarantee in a default situation. These provisions make clear that as a threshold matter such a demand will be summarily rejected by EDA unless a lender establishes, with sufficient supporting documentation, that the borrower is in uncured default on any installment for more than 60 calendar days, all reasonable workout attempts have failed, and all business personal property securing the defaulted ITM Program loan has been liquidated. With respect to a lender's debt collection efforts, this subpart sets forth the requirements for a lender's liquidation and litigation plans that must be submitted before the lender undertakes such actions, outlines EDA's policies regarding a lender's liquidation of collateral and sale of ITM Program loans, and covers circumstances when EDA will pay its pro rata share of authorized legal fees and expenses. If EDA does purchase the guaranteed portion of an ITM Program loan from the lender, this subpart provides details about accrued interest payments and the applicable interest rate post-EDA purchase. Finally, similar to the SBA 7(a) program's "denial of liability" regulations, these regulations provide that, despite a lender's demand, EDA will be released from liability on a loan guarantee if EDA determines that one or more of ten events have occurred. Such events include a lender's failure to materially comply with any ITM Program requirement, a lender's misrepresentation (or failure to disclose) of a material fact regarding a guaranteed loan, and where a lender's improper action has put EDA at risk.

Subpart L—Enforcement Actions

Subpart L focuses on enforcement actions that EDA can take against lenders. Discussed are proper grounds for an enforcement action (*e.g.,* failure to maintain eligibility requirements for the SBA Preferred Lenders Program), types of enforcement actions that EDA may take (*e.g.,* suspension or revocation from the ITM Program), and general procedures for enforcement actions against lenders (*e.g.,* notice of action, Lender's opportunity to object, final agency decision).

Regulatory Flexibility Act

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities, for the following reasons: First, the Agency emphasizes that possible participation in the ITM program by small entities, whether from the lending or borrowing side, is entirely voluntary. Second, this rulemaking is not projected to adversely impact small lenders or borrowers since it does not impose any greater burden with respect to forms, fees, due diligence, or servicing than any other Federal loan guarantee program. The application forms closely match those of already existing loan guarantee programs, most notably SBA's 7(a) loan guarantee program, and the fees are similarly commensurate. As evidenced by these proposed regulations and forthcoming ITM program procedure manuals, reporting, due diligence, and other processes will be a stream-lined version of existing programs which will make the ITM program less burdensome for small entities to use than other programs. As such, the Chief Counsel certifies that this proposed rule will not have a significant impact on a substantial number of small entities.

Executive Orders No. 12866 and No. 13563

This proposed rule was drafted in accordance with Executive Orders 12866 and 13563. It was reviewed by the Office of Management and Budget (OMB), which found the proposed rule to be "significant" as that term is defined in Executive Order 12866 and Executive Order 13563. Accordingly, the proposed rule has undergone interagency review.

Congressional Review Act

This proposed rule is not major under the Congressional Review Act (5 U.S.C. 801 *et seq.*).

Executive Order No. 13132

It has been determined that this proposed rule does not contain policies with federalism implications as that term is defined in under Executive Order 13132.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) ("PRA") requires that a Federal agency consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the PRA unless that collection displays a currently valid OMB Control Number.

The following table provides a complete list of the collections of information (and corresponding OMB Control Numbers) set forth in this proposed rule. These collections of information are necessary for the proper performance and functions of EDA.

Part or section of this final rule	Nature of request	Form/title/OMB control No.
311.4; 311.5; 311.6	An applicant must provide information to demonstrate that it meets the eligibility criteria including credit availability.	ED–1920, Lender's Application.
311.8; 311.9; 311.501	An applicant must provide information to show that the proceeds will be used for an eligible use.	ED–1920, Lender's Application; ED–1050, Settlement Sheet; ED–172, Account Transcripts.
311.10	For property that is purchased with guaranteed funds, an applicant must supply information indicating that the criteria for leasing or renting a property is met before leasing or renting it.	ED–1920, Lender's Application.
311.11; 311.801	A Lender must supply written assurances to EDA that it will abide by certain ethical requirements.	ED–1920, Lender's Application.
311.6(n); 311.6(o); 311.11(b)	An applicant must supply information and certify that there are not any conflicts of interest between the Lender, Borrower, and EDA.	ED–1919, Borrower's Information Form; ED–1920, Lender's Application.
311.6(m); 311.11(d); 311.11(g); 311.12(a).	An applicant must supply information and certify that it does not have any Associates who render the applicant ineligible by being incarcerated, on probation, or on parole or have been indicted for a felony or a crime of moral turpitude.	ED–1919, Borrower's Information Form; ED–1920, Lender's Application; ED–912, Statement of Personal History.
311.12; 311.13(a)	An applicant must supply adequate information to show that the Borrower (including an Operating Entity) is creditworthy and all loans are sufficiently sound as to reasonably assure repayment. A personal guarantee may be required of a Borrower's Associates.	ED–1920, Lender's Application; ED–413, Personal Financial Statement.
311.100; 311.101; 311.102; 311.103; 311.104; 311.105; 311.106.	Applicants must supply written assurances to EDA that it will abide by the requirements imposed under other laws, restrictions, and orders.	ED–1919, Borrower's Information Form; ED–413, Personal Financial Statement.
311.300; 311.801(e)	Lenders must provide information demonstrating that they are SBA Preferred Lenders in good standing.	ED–1920, Lender's Application.
311.400	Lenders must agree to submit servicing reports to EDA on a monthly basis for every outstanding loan.	ED–1502, Monthly Servicing Report.
311.401; 311.702; 311.703; 311.803.	Applicants for ITM Program loans must identify to EDA the name of each agent that helped the applicant obtain the loan, describing the services performed, and disclosing the amount of each fee paid or to be paid by the applicant to the agent in conjunction with the performance of those services.	ED–159, Fee Disclosure and Compensation Agreement; ED–1050, Settlement Sheet.
311.600	Applicants must supply adequate information to certify that the guarantee percentage is 80 percent or less of the entire loan obligation.	ED–1920, Lender's Application.
311.601	An applicant must supply information and certify that the entire loan obligation is $10 million or less unless a loan amount of up to $15 million is approved by the Deputy Assistant Secretary on a an individual case-by-case basis.	ED–1920, Lender's Application.
311.602	The applicant must supply information to indicate that the loan term is the lesser of 30 years or 90% of the projected useful life of the physical asset to be financed by the obligation, as determined by the Deputy Assistant Secretary.	ED–1920, Lender's Application.
311.603; 311.604	The Lender must supply written certification that it agrees to certain interest rates limits.	ED–1920, Lender's Application.
311.700(a); 311.700(c)	If the Borrower seeks to increase or decrease the total loan amount or change the guarantee percentage of an ITM Program loan, the Borrower must have supplied information that indicates agreement to an increase in the guarantee fee. A Borrower must further supply written documentation that indicates acknowledgment that a refund of the guarantee fee will occur only if the decrease in the loan amount happens before the first disbursement.	ED–2237, Approval Action Modification Form.
311.701	Lender must supply information that shows it agrees to pay the servicing fee on a monthly basis while submitting the monthly servicing report.	ED–1502, Monthly Servicing Report.
311.801(a)(2)	Lenders must supply loan transaction data to EDA and maintain satisfactory performance as determined by EDA through analysis of that data.	ED–1502, Monthly Servicing Report.

Part or section of this final rule	Nature of request	Form/title/OMB control No.
311.900; 311.901; 311.904	Before modifying loan terms, Lenders must supply the proposed modification information to EDA and request authorization from EDA to changes to loan terms including but not limited to changes in the loan amount, an extension of maturity, and any other changes to the loan that effect EDA's risk.	ED–2237, Approval Action Modification Form.
311.1000(a); 311.1000(b)	A Lender must supply written confirmation that it agrees to refrain from requesting a purchase of a defaulted loan by EDA until the Borrower has been in default for a minimum of 60 days.	ED–1149, Transcript of Account.
311.1000(b); 311.1004(a)	The Lender must provide the documentation to prove the loan has been closed, serviced, and liquidated in a prudent manner and in compliance with ITM program regulations.	ED–159, Fee Disclosure and Compensation Agreement; ED–1050, Settlement Sheet; ED–1149, Transcript of Account.

Regulatory Text

For the reasons set forth in the preamble, EDA proposes to amend title 13, chapter III of the Code of Federal Regulations by adding part 311 to read as follows:

PART 311—INNOVATIVE TECHNOLOGIES IN MANUFACTURING LOAN GUARANTEE PROGRAM

Subpart A—General Provisions

Sec.
311.1 Purpose and scope of the Innovative Technologies in Manufacturing Loan Guarantee Program.
311.2 Description of Innovative Technologies in Manufacturing Loan Guarantee Program.
311.3 Definitions.
311.4 Basic eligibility criteria.
311.5 Credit unavailable elsewhere.
311.6 Ineligible types of businesses.
311.7 Conditions required of an eligible passive entity.
311.8 Eligible uses of proceeds.
311.9 Restrictions on uses of proceeds.
311.10 Leasing part of a building to another business.
311.11 Lender ethical requirements.
311.12 Lending criteria.
311.13 Loan conditions.

Subpart B—Requirements Imposed Under Other Laws and Orders

311.100 Flood insurance.
311.101 Compliance with child support obligations.
311.102 Flood-plain and wetlands management.
311.103 Lead-based paint.
311.104 Earthquake hazards.
311.105 Coastal barrier islands.
311.106 Compliance with other laws.

Subpart C—Applicability and Enforceability of Loan Program Requirements

311.200 Lender compliance with loan program requirements.
311.201 Status of lenders.
311.202 Status of borrowers.

Subpart D—Loan Applications

311.300 Applying for a loan.
311.301 The contents of an ITM Program application.
311.302 Approval or denial.
311.303 Reconsideration after rejection.

Subpart E—Reporting

311.400 Monthly servicing report
311.401 Disclosure of fees.
311.402 Notifying DOC's Office of Inspector General of suspected fraud.

Subpart F—Limitations on Use of Proceeds

311.500 Refinancing unsecured or under-secured loans.

Subpart G—Maturities; Interest Rates; Loan and Guarantee Amounts

311.600 Percentage of a loan eligible for an ITM Program guarantee.
311.601 Loan size limits.
311.602 Limits on loan maturities.
311.603 Fixed interest rate loans.
311.604 Variable interest rate loans.

Subpart H—Fees

311.700 Guarantee fee.
311.701 Monthly servicing fee.
311.702 Fees the lender may collect from a loan applicant.
311.703 Fees that the lender or associate may not collect from the borrower or share with third parties.

Subpart I—Participation Criteria

311.800 Authorization terms.
311.801 Requirements for all participating lenders.
311.802 Preferences.
311.803 Other services lenders may provide borrowers.
311.804 Advertisement of relationship with EDA.
311.805 Securitization and transfer.

Subpart J—Loan Modifications and Servicing Actions

311.900 Deferment of payment.
311.901 Extension of maturity.
311.902 Loan moratoriums..
311.903 Standards for lender loan servicing, loan liquidation, and debt collection litigation.
311.904 Servicing and liquidation actions that require the prior written consent of EDA.

Subpart K—EDA Purchase of a Guaranteed Portion

311.1000 Purchase of loan guarantees.
311.1001 Applicable interest rate after EDA purchases the guranteed portion of an ITM Program loan.
311.1002 Payment of accrued interest to the lender when EDA purchases the guaranteed portion.
311.1003 Earliest uncured payment default.
311.1004 Release of EDA's liability.
311.1005 Liquidation and litigation plans.
311.1006 Payment by EDA of legal fees and other expenses.
311.1007 EDA's policies concerning the liquidation of collateral and the sale of ITM Program loans.
311.1008 Loan asset sales.

Subpart L—Enforcement Actions

311.1100 Grounds for enforcement actions.
311.1101 Types of enforcement actions—lenders.
311.1102 General procedures for enforcement actions against lenders.

Authority: 15 U.S.C. 3701 *et seq.;* Department of Commerce Organization Order 10–4.

Subpart A—General Provisions

§ 311.1 Purpose and Scope of the Innovative Technologies in Manufacturing Loan Guarantee Program.

(a) As required by the Stevenson-Wydler Technology Innovation Act of 1980, a loan guarantee may be made under the Innovative Technologies in Manufacturing Loan Guarantee Program only for a project that re-equips, expands, or establishes a manufacturing facility in the United States: To use an innovative technology or an innovative process in manufacturing; to manufacture an innovative technology product or an integral component of such a product; or to commercialize an innovative product, process, or idea that was developed by research funded in whole or in part by a grant from the Federal government. See 15 U.S.C. 3721(b). The Stevenson-Wydler Technology Innovation Act of 1980 defines an "innovative technology" as a technology that is significantly improved as compared to the technology in general use in the commercial marketplace in the United States at the time the loan guarantee is issued. See 15 U.S.C. 3721(s)(3). Similarly, the term "innovative process" is defined as a process that is significantly improved as compared to the process in general use in the commercial marketplace in the United

States at the time the loan guarantee is issued. See 15 U.S.C. 3721(s)(2).

(b) The Secretary of Commerce has delegated the responsibility of implementing and administering the Innovative Technologies in Manufacturing ("ITM") Program, which includes promulgating regulations as required by the Stevenson-Wydler Technology Innovation Act of 1980 (see 13 U.S.C. 3721(l)), to EDA.

§ 311.2 Description of Innovative Technologies in Manufacturing Loan Guarantee Program.

A loan is initiated by a Lender agreeing to make an ITM Program-qualifying loan to a borrower. The lender applies to the ITM Program on a loan-by-loan basis. If EDA agrees to guarantee a portion of the loan, the lender funds and services the loan. If the borrower defaults on the loan, EDA's guarantee requires EDA to purchase its portion of the outstanding balance upon demand by the lender and subject to verification that program requirements have been met.

§ 311.3 Definitions.

As used in this part, the following terms shall have the following meanings:

Act means section 26 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3721 *et seq.*).

Agency means the Economic Development Administration within the U.S. Department of Commerce.

Assistant Secretary means the Assistant Secretary of Commerce for Economic Development.

Associate means the following:

(1) An *associate of a lender* means:

(i) An officer, director, or holder of 5 percent or more of the value of the lender's stock or debt instruments, or an agent involved in the loan process; or

(ii) Any entity in which one or more individuals referred to in paragraph (1)(i) of this definition or a close relative of any such individual owns or controls at least 5 percent.

(2) An *associate of a borrower* means:

(i) An officer, director, designated representative, or owner of more than 5 percent of the borrower's equity;

(ii) Any entity in which one or more individuals referred to in paragraph (2)(i) of this definition or a close relative of any such individual owns or controls at least 5 percent of the borrower's equity;

(iii) Any entity in which the borrower owns or controls at least 5 percent; or

(iv) Any entity holding convertible debt that could result in ownership of at least 5 percent of the borrower wherein the convertible debt is eligible for conversion during the time period discussed in paragraph (3) of this definition.

(3) For purposes of this definition, the time during which an associate relationship exists commences six months before the following dates and continues as long as the certification, participation agreement, or loan is outstanding:

(i) For a lender, the date of application for a loan guarantee on behalf of an applicant; or

(ii) For a borrower, the date of the loan application to EDA, or the lender.

Bank regulatory agencies means the Federal Deposit Insurance Corporation, the Federal Reserve Board, and the Office of the Comptroller of the Currency.

Borrower means the person or persons who executed the loan instruments evidencing ITM Program-guaranteed loan.

Chief Counsel means the Chief Counsel of EDA.

Close relative means a spouse or partner; a lineal descendent, a lineal ascendant; a sibling; or the spouse of any such person.

Department of Commerce, Department, or *DOC* means the U.S. Department of Commerce.

Eligible passive entity means an entity or trust that does not engage in regular and continuous business activity, but does lease or otherwise provide real or personal property to an operating entity for use in the operating entity's business, and complies with the conditions set forth in § 311.7.

Guarantor means a person who executed a guarantee as security for a loan instrument executed by a borrower.

ITM Program loan proceeds means the proceeds paid to a borrower from a lender pursuant to an ITM Program loan.

Innovative technological project or *project* is defined as having all of the following criteria:

(1) *Innovative,* which is defined as:

(i) A significant improvement in function, performance, reliability, or quality of a product or service in comparison to commercial technologies currently in use; and

(ii) The ability for such products or services to be sold based on those improvements.

(2) Technological in nature, which is defined as relying on the principles of one of the following sciences: engineering, physical sciences, computer sciences, or biological sciences.

(3) Producing one of the following:

(i) A significantly improved product or process; or

(ii) A combination of existing products or processes that result in significantly reduced factor inputs without sacrificing product quality, production throughput, or economies of production.

(4) Resulting in one of the following actions:

(i) Utilizing this innovative technology in the process of manufacturing an existing product;

(ii) Utilizing an existing product where the delivery is the innovative technology;

(iii) Manufacturing a new innovative technology; or

(iv) Commercializing an innovative technology that was developed by research funded in part or in whole by Federal grant funding.

Lender means an institution that is a lender in good standing under the SBA Preferred Lenders Program. Additional eligible institutions may be permitted from time to time at the discretion of the Assistant Secretary.

Loan instruments means the authorization, note, instruments of hypothecation, and all other agreements and documents related to a loan.

Loan program requirements means requirements imposed upon lenders by statute, EDA regulations, any agreement executed between the lender and EDA, official EDA notices and forms applicable to the ITM Program, and loan instruments; as such requirements are issued and revised by EDA from time to time.

Manufacturing means a business with a six-digit NAICS code between 311111–333999, and as such other codes as the Assistant Secretary may provide and publish in the **Federal Register**.

Management official means an officer, director, general partner, manager, employee participating in management, agent, or other participant in the management of the affairs of the lender's activities.

Medium-sized business means a business that has a maximum size that is twice the maximum size of a small business using the same six-digit NAICS code and same measurement standards as the calculation for a small business.

Obligor means a person with direct liability for repaying the loan such as the borrower and any assumptor, and every person with contingent liability such as the guarantor.

Operating entity means an eligible small or medium-sized business actively involved in conducting business operations currently or about to be located on real property owned by an eligible passive entity, or using or about to use in its business operations personal property owned by an eligible passive entity.

Person means any individual, corporation, partnership, association, unit of government, or legal entity, however organized.

Preference means any arrangement giving a lender a preferred position compared to EDA relating to the making, servicing, or liquidation of a loan with respect to such things as repayment, collateral, guarantees, control, maintenance of a compensating balance, purchase of a certificate of deposit or acceptance of a separate or companion loan, without EDA's consent.

Project means an Innovative Technological Project as defined in this section.

Rentable property means the total square footage of all buildings or facilities used for business operations.

SBA or *Small Business Administration* means the U.S. Small Business Administration.

SBA Preferred Lenders Program means the SBA Preferred Lenders Program under 13 CFR 120.450 through 120.453.

Service provider means an entity that contracts with a lender to perform management, marketing, legal or other services.

Small business means a business that is small in size by the most current SBA size standards in effect at the time of the application under 13 CFR 121.101 and 121.102 and clarified by any EDA SOPs in effect at the time.

Small or medium-sized business means, collectively, all small businesses and all medium-sized businesses.

SOPs means EDA Standard Operating Procedures, as may be issued and revised by EDA from time to time.

§ 311.4 Basic eligibility criteria.

To be an eligible borrower, an applicant must:

(a) Be an operating business (except for loans to eligible passive entities);

(b) Be organized as a for profit entity;

(c) Be located in the United States (includes territories and possessions);

(d) Be a small or medium-sized business, when including associates;

(e) Be prospectively or currently engaged in the manufacture of an Innovative Technological Project (except for loans to eligible passive entities);

(f) Be able to demonstrate a need for the desired credit per § 311.5; and

(g) Agree to use a federally-approved electronic employment eligibility verification system to verify the employment eligibility of:

(1) All persons hired during the contract term or by the borrower to perform employment duties within the United States; and

(2) All persons assigned by the borrower to perform work within the United States on the project.

§ 311.5 Credit unavailable elsewhere.

EDA provides loan assistance only to applicants for whom the desired credit is not otherwise available on reasonable terms from non-Federal sources. EDA requires the lender to certify or otherwise show that the desired credit is unavailable to the applicant on reasonable terms and conditions from non-Federal sources without EDA assistance, taking into consideration the prevailing rates and terms in the community in or near where the applicant conducts business, for similar purposes and periods of time. Submission of an application to EDA by a lender constitutes certification by the lender that it has examined the credit-worthiness of the applicant, has based its certification upon that examination, and has justification in its file to support the certification.

§ 311.6 Ineligible types of businesses.

For those businesses that satisfy basic eligibility criteria under § 311.304, the following types of businesses are still deemed ineligible:

(a) Non-profit entities (for-profit subsidiaries are eligible);

(b) Financial businesses primarily engaged in the business of lending, such as banks, finance companies, and factors;

(c) Passive businesses owned by developers and landlords that do not actively use or occupy the assets acquired or improved with the loan proceeds (except eligible passive entities under § 311.7);

(d) Life insurance companies;

(e) Businesses located in a foreign country (businesses in the U.S. owned by aliens may qualify);

(f) Pyramid sale distribution plans;

(g) Businesses deriving more than one-third of gross annual revenue from legal gambling activities;

(h) Businesses engaged in any illegal activity;

(i) Private clubs and businesses which limit the number of memberships for reasons other than capacity;

(j) Government-owned entities (except for businesses owned or controlled by a Native American tribe);

(k) Businesses principally engaged in teaching, instructing, counseling or indoctrinating religion or religious beliefs, whether in a religious or secular setting;

(l) Consumer and marketing cooperatives (producer cooperatives are eligible);

(m) Businesses with an associate who is incarcerated, on probation, on parole, or has been indicted for a felony or a crime of moral turpitude;

(n) Businesses in which the lender, or any of its associates owns an equity interest;

(o) Businesses for which common ownership between the borrower and lender:

(1) Existed within six months of the submission of any of the loan instruments by the borrower and lender; or

(2) Commences existence between the borrower and lender at any time during the loan term;

(p) Businesses that:

(1) Present live performances of a prurient sexual nature; or

(2) Derive directly or indirectly more than de minimis gross revenue through the sale of products or services, or the presentation of any depictions or displays, of a prurient sexual nature;

(q) Unless waived by EDA for good cause:

(1) Business that have previously defaulted on a Federal loan or federally assisted financing, resulting in the Federal Government or any of its agencies or departments sustaining a loss in any of its programs, and businesses owned or controlled by an applicant or any of its associates which previously owned, operated, or controlled a business that defaulted on a Federal loan (or guaranteed a loan that was defaulted) and caused the Federal Government or any of its agencies or departments to sustain a loss in any of its programs. EDA reserves the right to waive this exception for a good cause, including any cases where the loss was paid in full. If a loss is paid in full then the loss may be processed using standard procedures. For purposes of this section, a compromise agreement shall also be considered a loss; or

(2) Business that have an outstanding delinquent Federal debt;

(r) Businesses primarily engaged in political or lobbying activities; and

(s) Business not prospectively or currently engaged in the manufacture of an Innovative Technological Project (except for loans to eligible passive entities).

§ 311.7 Conditions required of an eligible passive entity.

An eligible passive entity must use loan proceeds to acquire or lease, and/or improve or renovate, real or personal property (including eligible refinancing), that it leases to one or more operating entities for conducting the operating entity's business (references to operating entity in paragraphs (a) and (b) of this section mean each operating entity). Any ownership structure or legal form may qualify as an eligible passive entity.

(a) Conditions that apply to all legal forms:

(1) The operating entity must be an eligible small or medium-sized business, and the proposed use of the proceeds must be an eligible use if the operating entity were obtaining the financing directly;

(2) The eligible passive entity (with the exception of a trust) and the operating entity each must be a small or medium-sized business under the appropriate size standards defined in § 311.3;

(3) The lease between the eligible passive entity and the operating entity must be in writing and must be subordinated to any security interest EDA may have on the property. Also, the eligible passive entity (as landlord) must furnish as collateral for the loan an assignment of all rents paid under the lease;

(4) The lease between the eligible passive entity and the operating entity, including options to renew exercisable solely by the operating entity, must have a remaining term at least equal to the term of the loan;

(5) The operating entity must be a guarantor or co-borrower with the eligible passive entity. In an ITM Program loan that includes the purchase of other assets, including intangible assets, for the operating entity's use, the operating entity must be a co-borrower; and

(6) The eligible passive entity and the operating entity must guarantee the loan (the trustee shall execute the guarantee on behalf of any trust).

(b) Additional conditions that apply to trusts. The eligibility status of the trustor will determine trust eligibility. All donors to the trust will be deemed to have trustor status for eligibility purposes. A trust qualifying as an eligible passive entity may engage in other activities as authorized by its trust agreement. The trustee must warrant and certify that the trust will not be revoked or substantially amended for the term of the loan without the consent of EDA. The trustor must guarantee the loan. For purposes of this section, the trustee shall certify to EDA that:

(1) The trustee has authority to act;

(2) The trust has the authority to borrow funds, pledge trust assets, and lease the property to the operating entity;

(3) The trustee has provided accurate, pertinent language from the trust agreement confirming the above; and

(4) The trustee has provided and will continue to provide EDA with a true and complete list of all trustors and donors.

§ 311.8 Eligible uses of proceeds.

A borrower must use an ITM Program loan for sound business purposes. The uses of proceeds are prescribed in each loan's loan instruments. A borrower may use ITM Program loan proceeds to:

(a) Acquire land (by purchase or lease);

(b) Improve a site (*e.g.*, grading, streets, parking lots, landscaping), including up to 5 percent for community improvements such as curbs and sidewalks;

(c) Purchase one or more existing buildings;

(d) Convert, expand, or renovate one or more existing buildings;

(e) Construct one or more new buildings;

(f) Acquire (by purchase or lease) and install fixed assets;

(g) Refinance existing debt for eligible uses;

(h) Purchase inventory, supplies, and/or raw materials; and/or

(i) License or purchase licenses to the necessary intellectual property related to the Innovative Technological Project such as patents, trademarks, etc., as long as the licensure or purchased license will be used to make a product or improve a process consistent with an Innovative Technological Project.

§ 311.9 Restrictions on uses of proceeds.

EDA will not authorize nor may a borrower use loan proceeds for the following purposes (including the replacement of funds used for any such purpose):

(a) Payments, distributions, or loans to associates of the borrower (except for ordinary compensation for services rendered);

(b) Refinancing a debt that was not incurred for uses indicated in § 311.8;

(c) Floor plan financing or other revolving line of credit;

(d) Investments in real or personal property acquired and held primarily for sale, lease, or investment;

(e) A purpose that does not benefit the small or medium-sized business;

(f) Operating working capital;

(g) Paying past-due Federal, State, and local payroll taxes; or

(h) Any use restricted by any provision under this part.

§ 311.10 Leasing part of a building to another business.

A borrower may permanently lease up to 49 percent of the rentable property to one or more tenants if the borrower permanently occupies and uses no less than 51 percent of the rentable property for the Innovative Technological Project or Projects. The Projects need not be owned solely by the borrower as long as they are bona fide Projects. If the borrower is an eligible passive entity that leases 100 percent of the new building's space to one or more operating entities, the operating entity, or operating entities together, must follow the same rule set forth in this paragraph.

§ 311.11 Lender ethical requirements.

Lenders must act ethically and exhibit good character. Ethical indiscretion of an associate of a lender will be attributed to the lender. A lender must promptly notify EDA if it obtains information concerning the unethical behavior of an associate. The following are examples of such unethical behavior. A lender may not:

(a) Self-deal;

(b) Have a real or apparent conflict of interest with a business with which it is dealing (including any of its associates or an associate's close relatives) or EDA;

(c) Own an equity interest in a business that has received or is applying to receive EDA credit support (during the term of the loan or within 6 months prior to the loan application);

(d) Be incarcerated, on parole, or on probation;

(e) Knowingly misrepresent or make a false statement to EDA;

(f) Engage in conduct reflecting a lack of business integrity or honesty;

(g) Be a convicted felon, or have an adverse final civil judgment (in a case involving fraud, breach of trust, or other similar conduct) that would cause the public to question the lender's business integrity, taking into consideration such factors as the magnitude, repetition, harm caused, and remoteness in time of the activity or activities in question;

(h) Accept funding from any source that restricts, prioritizes, or conditions the types of businesses that the lender may assist under an EDA program;

(i) Fail to disclose to EDA all relationships between the business and its associates (including close relatives of associates), the lender, and/or the lenders financing the Innovative Technological Project of which the lender is aware or should be aware;

(j) Fail to disclose to EDA whether the loan will:

(1) Reduce the exposure of a lender or an associate of a lender in a position to sustain a loss;

(2) Directly or indirectly finance the purchase of real estate, personal property or services (including insurance) from the lender or an associate of the lender;

(3) Repay or refinance a debt due a lender or an associate of a lender; or

(4) Require the business or an associate (including close relatives of associates), to invest in the borrower (except for institutions which require an investment from all members as a condition of membership, such as a Production Credit Association);

(k) Issue a real estate forward commitment to a builder or developer;

(l) Cease being prospectively or currently engaged in the manufacture of an Innovative Technological Project (except for loans to eligible passive entities); or

(m) Engage in any activity that impairs, restricts, or otherwise limits the lender's objective judgment in evaluating the loan.

§ 311.12 Lending criteria.

The borrower (including an operating entity) must be creditworthy. Loans must be sufficiently sound as to reasonably assure repayment. When reviewing ITM Program applications, EDA will consider the follow factors of an applicant's, an applicant's associates, and any guarantors of the applicant:

(a) Character, reputation, and credit history;

(b) Experience and depth of management;

(c) Strength of the business;

(d) Past earnings, projected cash flow, and future prospects;

(e) Ability to repay the loan with earnings from the business;

(f) Sufficient invested equity to operate on a sound financial basis;

(g) Potential for long-term success;

(h) Nature and value of collateral (although inadequate collateral will not be the sole reason for denial of a loan request); and

(i) The effect any associates may have on the ultimate repayment ability of the applicant.

§ 311.13 Loan conditions.

The following requirements are normally required for all ITM Program loans:

(a) *Personal guarantees.* Holders of at least a 5 percent ownership interest must guarantee a percentage of the loan, as determined by the lender. For loans over $10 million, a personal guarantee will be determined by EDA. EDA, in its discretion, consulting with the lender, may require other appropriate individuals to guarantee the loan as well.

(b) *Appraisals.* Lenders shall use a prudent policy that is substantially comparable to non-guaranteed commercial loans.

(c) *Hazard Insurance.* EDA requires hazard insurance on all collateral. Lenders may use prudent policy that is similar to those requirements for substantially comparable non-guaranteed commercial loans.

(d) *Collateral.* Lenders shall use a prudent policy that is substantially comparable to non-guaranteed commercial loans.

(e) *Bonding requirements.* On loans that finance construction, the lender must use a construction management company or the borrower must supply a 100 percent payment and performance bond and builder's risk insurance, unless waived by EDA.

Subpart B—Requirements Imposed Under Other Laws and Orders

§ 311.100 Flood insurance.

Under the Flood Disaster Protection Act of 1973 (Sec. 205(b) of Pub. L. 93–234 (42 U.S.C. 4000 *et seq.*)), a loan recipient must obtain flood insurance if any building (including mobile homes), machinery, or equipment acquired, installed, improved, constructed, or renovated with the ITM Program loan proceeds is located in a special flood hazard area. The requirement applies also to any inventory, fixtures, or furnishings contained or to be contained in the building. Mobile homes on a foundation are buildings. If required, lenders must notify borrowers that flood insurance must be maintained.

§ 311.101 Compliance with child support obligations.

Any holder of 50% or more of the ownership interest in the borrower must certify that he or she is not more than 60 days delinquent on any obligation to pay child support arising under:

(a) An administrative order;

(b) A court order;

(c) A repayment agreement between the holder and a custodial parent; or

(d) A repayment agreement between the holder and a State agency providing child support enforcement services.

§ 311.102 Flood-plain and wetlands management.

(a) All loans must conform to requirements of Executive Orders 11988, "Flood Plain Management" (3 CFR, 1977 Comp., p. 117) and 11990, "Protection of Wetlands" (3 CFR, 1977 Comp., p. 121). Lenders must comply with requirements applicable to them. Applicants must show:

(1) Whether the location for which financial assistance is proposed is in a floodplain or wetland;

(2) If it is in a floodplain, that the assistance is in compliance with local land use plans; and

(3) That any necessary construction or use permits will be issued.

(b) Generally, there is an 8-step decision making process with respect to:

(1) Construction or acquisition, other than of a building;

(2) Repair and restoration equal to more than 50% of the market value of a building; or

(3) Replacement of destroyed structures.

(c) EDA may determine for the following types of actions, on a case-by-case basis, that the full 8-step process is not warranted and that only the first step (determining if a proposed action is in the base floodplain) need be completed:

(1) Actions located outside the base floodplain;

(2) Repairs, other than to buildings, that are less than 50% of the market value of the building;

(3) Replacement of building contents, materials, and equipment;

(4) Hazard mitigation measures; or

(5) EDA loan assistance of $1,500,000 or less, including ITM Program loans.

§ 311.103 Lead-based paint.

If loan proceeds are for the construction or rehabilitation of a residential structure, lead-based paint may not be used on any interior surface, or on any exterior surface that is readily accessible to children under the age of seven years.

§ 311.104 Earthquake hazards.

When loan proceeds are used to construct a new building or an addition to an existing building, the construction must conform with the "National Earthquake Hazards Reduction Program ("NEHRP") Recommended Provisions for the Development of Seismic Regulations for New Buildings" (which can be obtained from the Federal Emergency Management Agency, Publications Office, Washington, DC) or a code identified by EDA as being substantially equivalent.

§ 311.105 Coastal barrier islands.

Neither lenders nor EDA may make or guarantee any loan within the Coastal Barrier Resource System as a part of the ITM Program.

§ 311.106 Compliance with other laws.

All ITM Program loans are subject to all applicable laws, including (without limitation) all applicable environmental laws as well as civil rights laws and laws prohibiting discrimination on the grounds of race, color, national origin, religion, sex, marital status, disability or age. EDA may request agreements or evidence to support or document compliance with these laws, including reports required by applicable statutes or the regulations in this chapter.

Subpart C—Applicability and Enforceability of Loan Program Requirements

§ 311.200 Lender compliance with loan program requirements.

Lenders must comply and maintain familiarity with loan program requirements for the ITM Program, as such requirements are revised from time to time. Loan program requirements in effect at the time that a lender takes an action in connection with a particular loan govern that specific action. For example, although loan closing requirements in effect when a lender closes a loan will govern the closing actions, a lender's liquidation actions on the same loan are subject to the liquidation requirements in effect at the time that a liquidation action is taken.

§ 311.201 Status of lenders.

Lenders and their contractors are independent entities that are responsible for their own actions with respect to a loan. EDA has no responsibility or liability for any claim by a borrower, guarantor or other party alleging injury as a result of any allegedly wrongful action taken by a lender, an employee, an agent, or a contractor of a lender.

§ 311.202 Status of borrowers.

Borrowers and their contractors are independent entities that are responsible for their own actions with respect to a loan. EDA has no responsibility or liability for any claim by any entity alleging injury as a result of any allegedly wrongful action taken by a borrower, an employee, an agent, or a contractor of a borrower.

Subpart D—Loan Applications

§ 311.300 Applying for a loan.

An applicant for a loan seeking to participate in the ITM Program should apply to a lender who is an SBA preferred lender.

§ 311.301 The contents of an ITM Program application.

For most ITM Program loans, EDA requires that an ITM Program application contain, among other things, a description of the history and nature of the business, the amount and purpose of the loan, the lender's credit memorandum, the collateral offered for the loan, current financial statements, historical financial statements (or tax returns if appropriate) for the past three fiscal years, IRS tax verification, and a business plan, when applicable. Personal histories and financial statements may be required from the applicant and associates of the applicant (and the operating entity, if applicable).

§ 311.302 Approval or denial.

The lender will receive written notice of acceptance or rejection for participation in the ITM Program by EDA, and will pass the decision on to the applicant. Notice of rejection will include the reasons for rejection.

§ 311.303 Reconsideration after rejection.

If a lender believes the reasons for rejection have been overcome, the lender may submit a request for reconsideration to EDA along with a detailed written explanation of how the loan applicant has overcome the reason(s) for the rejection. The request must be submitted to EDA within 6 months of the rejection. Any request submitted more than 90 days after the date of the rejection must include current financial statements. The request for reconsideration will be reviewed by two officials designated by the Assistant Secretary. If the two officials agree on a decision (acceptance or rejection), the decision will be final. If the two officials do not agree, the Assistant Secretary will make the final decision. In either case, EDA will inform the lender, in writing, of the final decision.

Subpart E—Reporting

§ 311.400 Monthly servicing report.

Lenders must submit a servicing report to EDA on a monthly basis for every loan outstanding. EDA may request such loan servicing information including principal and interest payments, fee payments, loan status, and any additional information as the Assistant Secretary sees fit. Lenders may collect and store loan data using a prudent policy similar to their policy for non-guaranteed commercial loans.

§ 311.401 Disclosure of fees.

An applicant for an ITM Program loan must identify to EDA the name of each agent that helped the applicant obtain the loan, describing the services performed, and disclosing the amount of each fee paid or to be paid by the applicant to the agent in conjunction with the performance of those services. Form ED–159 provides full limitations on fee amounts and eligible services.

§ 311.402 Notifying DOC's Office of Inspector General of suspected fraud.

Lenders, borrowers, and EDA employees must notify the Department's Office of Inspector General of any information of which they are aware indicating that fraud may have occurred in connection with an ITM Program loan. Send the notification to the U.S. Department of Commerce, Office of Inspector General, 1401 Constitution Avenue NW., Washington, DC 20230, telephone (202) 482–4661.

Subpart F—Limitations on Use of Proceeds

§ 311.500 Refinancing unsecured or under-secured loans.

A borrower may not use ITM Program loan proceeds to pay any creditor in a position to sustain a loss causing a shift to EDA of all or part of a potential loss from an existing debt.

Subpart G—Maturities; Interest Rates; Loan and Guarantee Amounts

§ 311.600 Percentage of a loan eligible for an ITM Program guarantee.

EDA's guarantee percentage must not exceed the applicable percentage established in the Act. The maximum allowable guarantee percentage on a loan shall not exceed an amount equal to 80 percent of the obligation, as determined at the time at which the loan guarantee is issued.

§ 311.601 Loan size limits.

The maximum size for a loan that is eligible for the ITM Program is $10 million; however, loans as large as $15 million may be approved by the Assistant Secretary on a case-by-case basis.

§ 311.602 Limits on loan maturities.

The term of a loan shall be the lesser of 30 years or 90% of the projected useful life, as determined by the Assistant Secretary or designee, of the physical asset to be financed by the obligation.

§ 311.603 Fixed interest rate loans.

A loan may have a fixed interest rate based on EDA's maximum allowable rates as published periodically in the **Federal Register**.

§ 311.604 Variable interest rate loans.

A Lender may use a variable rate of interest, upon EDA's approval. EDA shall approve the use of a variable interest rate under the following conditions:

(a) *Frequency.* Any change in the interest rate may only occur on the first calendar day of a month, with the first change allowed in the first month following initial disbursement. The new rate will use the base rate (see paragraph (c) of this section) in effect on the first business day of the month.

(b) *Range of fluctuation.* The amount of fluctuation shall be equal to the movement in the base rate. The difference between the initial rate and the ceiling rate may be no greater than the difference between the initial rate and the floor rate.

(c) *Base rate.* The base rate will be one of the following:

(i) The prime rate as printed in a national financial newspaper published each business day;

(ii) The 3-month London Interbank Offered Rate (LIBOR) as printed in a national financial newspaper published each business day; or

(iii) Five-year Treasuries as printed in the Federal Reserve's H.15 release, as in effect on the first business day of the month.

(d) *Maximum spreads.* The maximum spread will be defined based on the base rate. A spread of 2.75 percentage points for prime rate, 5.75 percentage points for LIBOR rate, or 4.75 percentage points for Treasury rate will be the maximum allowed, unless otherwise decided by the Assistant Secretary and published in the **Federal Register**.

(e) *Amortization.* A lender is required to reamortize the loan on the first calendar day of the month following an interest rate change so that the loan will be paid off by the maturity date of the note, as amended. With prior approval of EDA, the lender may use a different amortization schedule; however, EDA does not permit amortization schedules that involve balloon notes or balloon payments.

(f) *Accrual method.* Lenders may use either a 30/360 or actual/365 accrual method for ITM Program loans (actual/366 in leap years). Actual/360 and other methods may not be used.

Subpart H—Fees

§ 311.700 Guarantee fee.

(a) *Amount of guarantee fee.* The guarantee fee that the lender must pay to EDA shall be published in the **Federal Register** prior to the first day of a fiscal year. Should the loan guarantee amount increase, the amount of the guarantee fee will correspondingly increase.

(b) *When the guarantee fee is payable.* The Lender must pay the guarantee fee to EDA within 90 days after EDA gives its loan approval. The lender may charge the borrower the fee after the lender has made the first disbursement of the loan. The borrower may use the loan proceeds to pay the guarantee fee. The first disbursement, however, must not be made solely or primarily to pay the guarantee fee.

(c) *Refund of guarantee fee.* EDA will refund the guarantee fee if the lender has not made any disbursement and the lender requests in writing the refund and cancellation of the EDA guarantee. If any disbursements have been made, the entire fee will be retained.

(d) *Payment of the guarantee fee.* The borrower may use non-revolving working capital loan proceeds to reimburse the lender for the guarantee fee. If the guarantee fee is not paid, EDA may terminate the guarantee.

(e) *Acceptance of the guarantee fee.* Acceptance of the guarantee fee by EDA shall not waive any right of EDA arising from the lender's misconduct or violation of any provision of this part, the guarantee agreement, the authorization, or other loan documents.

§ 311.701 Monthly servicing fee.

A lender must pay an on-going monthly servicing fee to EDA for each guaranteed loan it makes. If the servicing fee is not paid, EDA may terminate the guarantee. Acceptance of the servicing fee by EDA does not waive any right of EDA arising from a lender's or borrower's negligence, misconduct or violation of any provision of these regulations or the loan instruments. The servicing fee that the lender must pay to EDA shall be published in the **Federal Register** prior to the first day of a fiscal year and is due at the time of the monthly servicing report. Fees collected on a loan in which EDA refuses to pay the guarantee will not be refunded. The servicing fee cannot be charged to the borrower. EDA may institute a late fee charge for delinquent payments of the servicing fee to cover administrative costs associated with collecting delinquent fees.

§ 311.702 Fees the lender may collect from a loan applicant.

The lender may charge borrowers fees that are consistent with prudent policy and similar in all material respects to the fees assessed against non-guaranteed commercial loans. The fees contemplated in this section may include service and packaging fees, extraordinary servicing fees, out-of-pocket expenses, late payment fees, and prepayment fees, among others.

§ 311.703 Fees that the lender or associate may not collect from the borrower or share with third parties.

The lender or its associates may not:

(a) Require the applicant or borrower to pay the lender, an associate, or any party designated by either, any fees or charges for goods or services, including insurance, as a condition for obtaining an ITM Program loan (unless permitted by this part);

(b) Charge an applicant any commitment, bonus, broker, commission, referral or similar fee;

(c) Charge points or add-on interest; or

(d) Charge the borrower for legal services, unless they are hourly charges for requested services actually rendered.

Subpart I—Participation Criteria

§ 311.800 Authorization terms.

EDA may enter into an authorization with a lender to make ITM Program loans. Such an authorization does not obligate EDA to participate in any specific proposed loan that a lender may submit. The existence of an authorization does not limit EDA's rights to refuse to guarantee a specific loan or establish general ITM Program policies. An authorization shall include such detailed terms and conditions as the Assistant Secretary determines appropriate to:

(a) Protect the interests of the United States in the event of default; and

(b) Ensure all the patents and technology necessary are available to complete and operate the Innovative Technological Project for any borrower, including EDA in subrogation of the borrower as discussed in § 311.1000.

§ 311.801 Requirements for all participating lenders.

A lender must be in good standing under the SBA Preferred Lenders Program at all times to have any loans be eligible for the ITM Program. In addition, the lender must:

(a) Have a continuing ability to evaluate, process, close, disburse, service, liquidate, and litigate loans in its portfolio including, but not limited to:

(1) Not being under any capital limitations by the FDIC to support ITM Program lending activities (for lenders with a Federal Financial Institution Regulator, meeting capital requirements for an adequately capitalized financial institution is considered sufficient); and

(2) Maintaining satisfactory performance, as determined by EDA in its discretion. Factors may include, but are not limited to historical performance measures (such as default rate, purchase rate, and loss rate), timely and accurate remittance of fees and monthly servicing reports, loan volume to the extent it impacts performance measures, and other performance-related measurements and information (such as contribution toward EDA's ITM Program mission);

(b) Be open to the public for the making of such loans (not be a financing subsidiary, engaged primarily in financing the operations of an affiliate);

(c) Have continuing good character and reputation, and otherwise meet and maintain the ethical requirements of § 311.11;

(d) Be supervised and examined by:

(1) A Federal Financial Institution Regulator,

(2) A state banking regulator satisfactory to the SBA Preferred Lenders Program, or

(3) SBA in its capacity under the SBA Preferred Lenders Program;

(e) Certify that it is in good standing with SBA Preferred Lenders Program and, as applicable, with an SBA lender's state regulator satisfactory to the SBA Preferred Lenders Program and Federal Financial Institution Regulator;

(f) Operate in a safe and sound condition using commercially reasonable lending policies, procedures, and standards employed by prudent lenders in the SBA Preferred Lenders Program; and

(g) Allow the Assistant Secretary and the Comptroller General of the United States, or their duly authorized representatives, access to records and other pertinent documents for the purpose of conducting an audit in a reasonable and timely manner.

§ 311.802 Preferences.

An agreement to participate under the Act may not establish any preferences in favor of the lender.

§ 311.803 Other services lenders may provide borrowers.

Subject to § 311.11 lenders, their associates, or the designees of either may provide services to and contract for goods with a borrower only after full disbursement of the loan to the business or to an account not controlled by the lender, its associate, or the designee. A lender, an associate, or a designee providing such services must do so under a written contract with the borrower, based on time and hourly, or fee for service charges, and must maintain time and billing records for examination by EDA. Fees cannot exceed those charged by established professional consultants providing similar services.

§ 311.804 Advertisement of relationship with EDA.

A Lender may refer in its advertising to its participation with EDA. The advertising may not:

(a) State or imply that the lender, or any of its borrowers, has or will receive preferential treatment from EDA;

(b) Be false or misleading; or

(c) Make use of DOC's or EDA's seals, emblems, insignias, or logos.

§ 311.805 Securitization and transfer.

No participating lender may securitize or otherwise, sell all or a participating portion of an ITM Program loan, or pledge an ITM Program loan without seeking and obtaining approval from the Assistant Secretary and executing a separate securitization agreement with EDA prior to securitizing. Securitization is governed by the provisions of that agreement, any related SOPs, and EDA's relevant regulations.

Subpart J—Loan Modifications and Servicing Actions

§ 311.900 Deferment of payment.

The lender may request, and EDA may agree, to defer principal, interest, or both principal and interest payments on a loan for a stated period of time, and use such other methods as it considers necessary and appropriate to help in the successful operation of the borrower.

§ 311.901 Extension of maturity.

EDA may agree to extend the maturity of a loan for up to 10 years beyond its original maturity if the extension will aid in the orderly repayment of the loan provided that the borrower maintains sufficient collateral.

§ 311.902 Loan moratoriums.

EDA may assume a borrower's obligation to repay principal and interest on a loan by agreeing to make the payments to the Lender on behalf of the borrower under terms and conditions set by EDA. This relief is called a "moratorium." Complete information concerning this program may be obtained from EDA.

§ 311.903 Standards for lender loan servicing, loan liquidation, and debt collection litigation.

(a) *Service using prudent lending standards.* Lenders must service ITM Program loans in their portfolio no less diligently than their non-ITM Program portfolio, and in a commercially reasonable manner, consistent with prudent lending standards, and in accordance with loan program requirements. Lenders that maintain an ITM Program loan portfolio must adhere to the same prudent lending standards for loan servicing followed by commercial lenders on loans without a government guarantee.

(b) *Liquidate using prudent lending standards.* Lenders must liquidate and conduct debt-collection litigation for ITM Program loans in their portfolio no less diligently than for their non-ITM Program portfolio. Lenders must do so in a prompt, cost-effective and commercially reasonable manner, consistent with prudent lending standards, and in accordance with loan program requirements and with any EDA approval of either a liquidation or litigation plan or any amendment of such a plan. Lenders that do not maintain a non-ITM Program loan portfolio must adhere to the same prudent lending standards followed by commercial lenders that liquidate loans without a government guarantee. They must also agree to operate in accordance with loan program requirements and with any EDA approval of either a liquidation or litigation plan or any amendment of such a plan.

(c) *EDA rights to take over servicing or liquidation.* EDA may, in its sole discretion, undertake the servicing, liquidation and/or litigation of any ITM Program loan. If EDA elects to service, liquidate, and/or litigate a loan, it will notify the relevant lender in writing, and, upon receiving such notice, the lender must assign the loan instruments to EDA and provide any needed assistance to allow EDA to service, liquidate, and/or litigate the loan. EDA will notify the borrower of the change in servicing. EDA may use contractors to perform these actions.

§ 311.904 Servicing and liquidation actions that require the prior written consent of EDA.

(a) *Actions by lenders.* Except as otherwise provided in a supplemental authorization with a lender, EDA must give its prior written consent before a lender takes any of the following actions:

(1) Increases the principal amount of a loan above that authorized by EDA at loan origination.

(2) Confers a preference on the lender or engages in an activity that creates a conflict of interest.

(3) Compromises the principal balance of a loan.

(4) Takes title to any property in the name of EDA.

(5) Takes title to environmentally contaminated property, or takes over operation and control of a business that handles hazardous substances or hazardous wastes.

(6) Transfers, sells or pledges a loan.

(7) Substantially alters the terms or conditions of any loan instrument.

(8) Releases collateral so as to cause the liquidation value of the remaining collateral to be less than 110% of the remaining outstanding balance of the loan.

(9) Accelerates the maturity of the note.

(10) Compromises or releases any claim against any borrower or obligor, or against any guarantor, standby creditor, or any other person that is contingently liable for moneys owed on the loan.

(11) Accepts a workout plan to restructure the material terms and

conditions of a loan that is in default or liquidation.

(12) Takes any action for which prior written consent is required by a loan program requirement.

(b) *Documentation requirements.* For all servicing/liquidation actions not requiring EDA's prior written consent, Lenders must document the justifications for their decisions and retain those and any supporting documents in their file for future EDA review to determine if the actions taken by the lender were prudent, commercially reasonable, and compliant with all ITM Loan Program Requirements.

Subpart K—EDA Purchase of a Guaranteed Portion

§ 311.1000 Purchase of loan guarantees.

(a) *When EDA will purchase.* A lender may demand in writing that EDA honor its guarantee if the Borrower is in uncured default on any installment for more than 60 calendar days (or less if EDA agrees), all reasonable workout attempts have failed, and all business personal property securing the defaulted ITM Program loan has been liquidated. The borrower must be in uncured default for at least 60 days prior to the lender beginning any liquidation. A lender may also submit a request for purchase of a defaulted ITM Program loan when a borrower files for Federal bankruptcy as long as a period of at least 60 days has elapsed since the last full installment payment. If a borrower cures a default before a lender requests purchase by EDA, the lender's right to request purchase on that default lapses. EDA considers liquidation of business personal property collateral to be completed when a lender has exhausted all prudent and commercially reasonable efforts to collect upon these assets. In addition, EDA, in its sole discretion, may purchase the guaranteed portion of a loan at any time whether in default or not, with or without the request from a lender.

(b) *Documentation for purchase.* EDA will not purchase its guaranteed portion of a loan from a lender unless the lender has submitted to EDA documentation that EDA deems sufficient to allow EDA to determine whether purchase of the guarantee is warranted under § 311.1004.

(c) *No waiver of EDA's rights.* Purchase by EDA of the guaranteed portion of a loan, or of a portion of EDA's guarantee of a loan, either through a negotiated agreement with a lender or otherwise, does not waive any of EDA's rights to recover from the responsible lender any money paid on the guarantee based upon the occurrence of any of the events set forth in § 311.1004 in connection with that loan.

(d) *EDA's rights of subrogation.* If EDA makes a payment under § 311.1000, EDA shall be subrogated to the rights, as specified in the loan instruments, of the recipient of the payment or related agreements. EDA's rights with respect to any property acquired pursuant to the loan instruments or related agreement shall be superior to the rights of any other person with respect to that property. These rights include, if appropriate, the authority (notwithstanding any other provisions of the law):

(1) To complete, maintain, operate, lease, or otherwise dispose of any property acquired pursuant to such loan guarantee or related agreement; or

(2) To permit the borrower, pursuant to an agreement with EDA, to continue to pursue the purposes of the project if the Assistant Secretary determines that such an agreement is in the public interest.

§ 311.1001 Applicable interest rate after EDA purchases the guaranteed portion of an ITM Program loan.

When EDA purchases the guaranteed portion of a fixed interest rate loan, the rate of interest remains as stated in the note. On loans with a variable interest rate, the interest rate that the Borrower owes will be at the rate in effect at the time of the earliest uncured payment default, or the rate in effect at the time of purchase if no default has occurred.

§ 311.1002 Payment of accrued interest to the lender when EDA purchases the guaranteed portion.

(a) *Rate of interest.* If EDA purchases the guaranteed portion from a lender, it will pay accrued interest at:

(1) The rate in the note if it is a fixed rate loan; or

(2) The rate in effect on the date of the earliest uncured payment default, or of EDA's purchase (if there has been no default).

(b) *Payment to lender.* EDA will pay up to a maximum of 180 days interest to a lender at the time of guarantee purchase.

§ 311.1003 Earliest uncured payment default.

The earliest uncured payment default is the date of the earliest failure by a borrower to pay a regular installment of principal and/or interest when due. Payments made by the borrower before a lender makes its request to EDA to purchase are applied to the earliest uncured payment default with payment first applied to outstanding accrued interest then principal. If the installment is paid in full, the earliest uncured payment default date will advance to the next unpaid installment date. If a borrower makes any payment after the lender makes its request to EDA to purchase, the earliest uncured payment default date does not change because the lender has already exercised its right to request purchase.

§ 311.1004 Release of EDA's liability.

(a) EDA is released from liability on a loan guarantee (in whole or in part, within EDA's exclusive discretion), if any of the events below occur:

(1) The lender has failed to comply materially with any loan program requirement for ITM Program loans.

(2) The lender has failed to make, close, service, or liquidate a loan in a prudent manner;

(3) The lender's improper action or inaction has placed EDA at risk;

(4) The lender has failed to disclose a material fact to EDA regarding a guaranteed loan in a timely manner;

(5) The lender has misrepresented a material fact to EDA regarding a guaranteed loan;

(6) EDA has received a written request from the lender to terminate the guarantee;

(7) The lender has not paid the guarantee fee within the period required under EDA rules and regulations;

(8) The lender has failed to request that EDA purchase a guarantee within 180 days after the maturity date of the loan. Notwithstanding, if the lender is conducting liquidation or debt collection litigation in connection with a loan that has matured, EDA will be released from its guarantee only if the lender fails to request that EDA purchase the guarantee within 180 days after the completion of the liquidation or debt collection litigation;

(9) The lender has failed to use required EDA forms or exact electronic copies; or

(10) The borrower has paid the loan in full.

(b) If EDA determines, at any time, that any of the events set forth in paragraph (a) of this section occurred in connection with that loan, EDA is entitled to recover any moneys paid on the guarantee plus interest from the lender responsible for those events.

(c) If the lender's loan documentation or other information indicates that one or more of the events in paragraph (a) of this section occurred, EDA may undertake such investigation as it deems necessary to determine whether to honor or deny the guarantee, and may withhold a decision on whether to honor the guarantee until the completion of such investigation.

(d) Any information provided to EDA by a lender or other party will not prejudice, or be construed as any waiver of, EDA's right to deny liability for a guarantee if one or more of the events listed in paragraph (a) of this section occur.

(e) Unless EDA provides written notice to the contrary, the lender remains responsible for all loan servicing and liquidation actions until EDA honors its guarantee in full.

§ 311.1005 Liquidation and litigation plans.

(a) *EDA oversight.* EDA may monitor or review liquidation through the review of liquidation plans that lenders must submit to EDA for approval prior to undertaking liquidation, and through liquidation wrap-up reports that lenders must submit to EDA at the completion of liquidation. EDA will monitor debt collection litigation, such as judicial foreclosures, bankruptcy proceedings and other state and Federal insolvency proceedings, through the review of litigation plans, as set forth in this section.

(b) *Liquidation plan.* A lender must, prior to undertaking any liquidation, submit a written proposed liquidation plan to EDA and receive EDA's written approval of that plan.

(c) *Litigation plan.* A lender must obtain EDA's prior approval of a litigation plan before proceeding with any Non-Routine Litigation, as defined in paragraph (c)(1) of this section. EDA's prior approval is not required for routine litigation, as defined in paragraph (c)(2) of this section.

(1) Non-routine litigation includes:

(i) All litigation where factual or legal issues are in dispute and require resolution through adjudication;

(ii) Any litigation where legal fees are estimated to exceed $10,000;

(iii) Any litigation involving a loan where a lender has an actual or potential conflict of interest with EDA; and

(iv) Any litigation involving an ITM Program loan where the lender has made or is servicing a separate loan to the same borrower or an associate of the borrower that is not an ITM Program loan.

(2) Routine litigation means uncontested litigation, such as non-adversarial matters in bankruptcy and undisputed foreclosure actions, having estimated legal fees not exceeding $10,000.

(d) *Decision by EDA to take over litigation.* If a lender is conducting, or proposes to conduct, debt collection litigation on an ITM Program loan, EDA may take over the litigation if EDA determines that the outcome of the litigation could adversely affect EDA's administration of the ITM Program or that the Government is entitled to legal remedies that are not available to the Lender. Examples of cases that could adversely affect EDA's administration of the ITM Program include, but are not limited to, situations where EDA determines that:

(1) The litigation involves important governmental policy or program issues;

(2) The case is potentially of great precedential value or there is a risk of adverse precedent to the Government;

(3) The lender has an actual or potential conflict of interest with EDA;

(4) The legal fees of the lender's outside counsel are unnecessary, unreasonable, or not customary in the locality; or

(5) The litigation adversely affects EDA's financial interest in the loan.

(e) *Amendments to a liquidation or litigation plan.* Lenders must submit an amended liquidation or litigation plan to address any material changes arising during the course of the liquidation or litigation that were not addressed in the original plan or an amended plan. Lenders must obtain EDA's written approval of the amended plan prior to taking any further liquidation or litigation action. Examples of such material changes that would require the approval of an amended plan include, but are not limited to:

(1) Changes arising during the course of routine litigation that transform the litigation into non-routine litigation, such as when the debtor contests a foreclosure or when the actual legal fees incurred exceed $10,000;

(2) If EDA has approved a litigation plan where anticipated legal fees exceed $10,000, or has approved an amended plan, and thereafter the anticipated or actual legal fees increase by more than 15 percent of the amount in the plan most recently approved by EDA; or

(3) If EDA has approved a liquidation plan, or an amended plan, and thereafter the anticipated or actual costs of conducting the liquidation increase by more than 15 percent of the amount in the plan most recently approved by EDA.

(f) *Limited waiver of need for a written liquidation or litigation plan.* EDA may, in its sole discretion, and upon request by a Lender, waive the requirements of paragraphs (b), (c), or (e) of this section if the following conditions are met:

(1) One of the following extraordinary circumstances exists to warrant such a waiver:

(i) Expeditious action is needed to avoid the potential risk of loss on the loan or dissipation of collateral exists;

(ii) An immediate response is required to litigation by a borrower, guarantor or third party; or

(iii) Any other urgent reason as determined by EDA arises;

(2) The lender obtains EDA's written consent to such waiver before undertaking the palliative emergency action, if at all practicable;

(3) EDA's waiver will apply only to the specific action(s) that the lender has identified to EDA as being necessary to address the emergency; and

(4) The lender, as soon after the emergency as is practicable, submits a written liquidation or litigation plan to EDA or, if appropriate, a written amended plan, and may not take further liquidation or litigation action without written approval of such plan or amendment by EDA.

(g) *Appeals.* A lender that made loans under its authority that disagrees with EDA's decision pertaining to an original or amended liquidation plan, other than such portions of the plan that address litigation matters, may appeal this decision in writing within 30 days of the decision to an official designated by the Assistant Secretary. That official will review the original decision and make a final decision based on the information submitted with the original request and any additional information provided by the lender. The additional information should address any concerns identified by the initial reviewing official. If the issue under discussion is part of a litigation plan, the Chief Counsel for EDA will review the initial decision and any additional information submitted by the bank and make a final decision on the appeal.

§ 311.1006 Payment by EDA of legal fees and other expenses.

(a) *Legal fees EDA will not pay.* (1) EDA will not pay legal fees or other costs that a Lender incurs:

(i) In asserting a claim, cross claim, counterclaim, or third-party claim against EDA or in defense of an action brought by EDA, unless payment of such fees or costs is otherwise required by Federal law.

(ii) In connection with actions of a lender's outside counsel for performing non-legal liquidation services, unless authorized by EDA prior to the action.

(iii) In taking actions that solely benefit a lender and that do not benefit EDA, as determined by EDA.

(2) EDA will not pay legal fees or other costs a lender incurs in the defense of, or pay for any settlement or adverse judgment resulting from, a suit, counterclaim, or other claim by any borrower, guarantor, or other party that seeks damages based upon a claim that

the lender breached any duty or engaged in any wrongful actions, unless EDA expressly directed the lender to undertake the allegedly wrongful action that is the subject of the suit, counterclaim or other claim.

(b) *Legal fees EDA may decline to pay.* In addition to any right or authority EDA may have under law or contract, EDA may, in its discretion, decline to pay a lender for all, or a portion, of legal fees and/or other costs incurred in connection with the liquidation and/or litigation of an ITM Program loan under any of the following circumstances:

(1) EDA determines that the lender failed to perform liquidation or litigation promptly and in accordance with commercially reasonable standards, in a prudent manner, or in accordance with any loan program requirement or EDA approvals of either a liquidation or litigation plan or any amendment of such a plan.

(2) A lender fails to obtain prior written approval from EDA for any liquidation or litigation plan, or for any amended liquidation or litigation plan, or for any action set forth in § 311.902, when such approval is required by these regulations or a loan program requirement.

(3) If EDA has not specifically approved fees or costs identified in an original or amended liquidation or litigation plan under § 311.1005, and EDA determines that such fees or costs are not reasonable, customary or necessary in the locality in question. In such cases, EDA will pay only such fees as it deems are necessary, customary and reasonable in the locality in question.

(c) *Appeals—liquidation costs.* A lender that disagrees with a decision by EDA to decline to reimburse all, or a portion, of the fees and/or costs incurred in conducting liquidation may appeal this decision in writing within 30-calendar days of the decision to an official designated by the Assistant Secretary. The official designated by the Assistant Secretary will make the final decision. If the issue under discussion involves litigation expenses, the decision-making official will consult with the Chief Counsel prior to making a final determination.

(d) *Appeals—litigation costs.* A lender that disagrees with a decision by EDA to decline to reimburse all, or a portion, of the legal fees and/or costs incurred in conducting debt collection litigation may appeal this decision in writing within 30 calendar days of the decision to an official designated by the Assistant Secretary. The appeal may include additional information to assist in reaching a final decision. The final decision will be made by an official designated by the Assistant Secretary who was not involved in the initial decision. This official will consult with the Chief Counsel prior to making a final determination.

§ 311.1007 EDA's policies concerning the liquidation of collateral and the sale of ITM Program loans.

(a) *Liquidation policy.* EDA or the lender, with approval of EDA, may liquidate collateral securing a loan if the loan is in default.

(b) *Sale and conversion of loans.* Without the consent of the borrower, EDA may sell ITM Program loans to qualified bidders by means of competitive procedures at publicly advertised sales. Bidder qualifications will be set for each sale in accordance with the terms and conditions of each sale.

(c) *Disposal of collateral and assets acquired through foreclosure or conveyance.* EDA or the lender, with the consent of EDA, may sell real and personal property (including contracts and claims) pledged to secure a loan that is in default in accordance with the provisions of the related security instrument.

(1) *Competitive bids or negotiated sales.* Generally, EDA will offer loan collateral and acquired assets for public sale through competitive bids at auctions or sealed bid sales. The lender may use negotiated sales if consistent with its usual practice for similar non-EDA assets.

(2) *Lease of acquired property.* EDA and the lender will consider proposals for a lease if it appears a property cannot be sold advantageously and the lease may be terminated on reasonable notice upon receipt of a favorable purchase offer.

(d) *Recoveries and security interests shared.* EDA and the lender will share pro rata (in accordance with their respective interests in a loan) all loan payments or recoveries, including proceeds from asset sales, all reasonable expenses (including advances for the care, preservation, and maintenance of collateral securing the loan and the payment of senior lienholders), and any security interest or guarantee (excluding EDA's guarantee) which the lender or EDA may hold or receive in connection with a loan.

(e) *Guarantors.* Guarantors of financial assistance have no rights of contribution against EDA on an ITM Program loan. EDA is not deemed to be a co-guarantor with any other guarantors.

§ 311.1008 Loan asset sales.

(a) *General.* Loan asset sales are governed by this section.

(b) The lender will be deemed to have consented to EDA's sale of the loan (guaranteed and unguaranteed portions) in an asset sale conducted or overseen by EDA upon the occurrence of:

(1) EDA's purchase of the guaranteed portion from the lender, provided however, that if EDA purchased the guaranteed portion pursuant to §§ 311.1000 through 311.1003 prior to the lender's completion of all liquidation actions with respect to the loan, then EDA will not sell such loan in an asset sale until nine months from the date of EDA's purchase; or

(2) EDA receives written consent from the lender.

(c) For loans identified in paragraph (b)(1) of this section, the lender may request that EDA withhold the loan from an asset sale if the lender submits a written request to EDA within 15 business days of EDA's purchase of the guaranteed portion of the loan from the registered holder and if such request addresses the issues described in this subparagraph. The lender's written request must advise EDA of the status of the loan, the lender's plans for workout and/or liquidation, including any pending sale of loan collateral or foreclosure proceedings arranged prior to EDA's purchase that already are underway, and the lender's estimated schedule for restructuring the loan or liquidating the collateral. EDA will consider the lender's request and, based on the circumstances, EDA in its sole discretion may elect to defer including the loan in an asset sale in order to provide the lender additional time to complete the planned restructuring and/or liquidation actions.

(d) After EDA has purchased the guaranteed portion of a loan from the lender, the lender must continue to perform all necessary servicing and liquidation actions for the loan up to the point the loan is transferred to the purchaser in an asset sale. The lender also must cooperate and take all necessary actions to effectuate both the asset sale and the transfer of the loan to the purchaser in the asset sale.

Subpart L—Enforcement Actions

§ 311.1100 Grounds for enforcement actions.

(a) *Agreement.* By making ITM Program loans, EDA lenders automatically agree to the terms, conditions, and remedies in the loan program requirements, as promulgated or issued from time to time and as fully set forth in the authorization or other applicable participation, guaranty, or supplemental agreement.

(b) *Scope.* Upon determination that the grounds applicable to an enforcement action exist, EDA may undertake one or more of the actions listed in § 311.1101 or as otherwise authorized by law.

(c) *General grounds for enforcement actions.* Except as provided in paragraphs (d) and (e) of this section, the grounds that may trigger an enforcement action against a lender include:

(1) Failure to maintain eligibility requirements for SBA Preferred Lenders Program;

(2) Failure to comply materially with any requirement imposed by ITM Program requirements;

(3) Making a material false statement or failure to disclose a material fact to EDA. A material fact includes but is not limited to any fact that is necessary to make a statement not misleading in light of the circumstances under which the statement was made;

(4) Not performing underwriting, closing, disbursing, servicing, liquidation, litigation or other actions in a commercially reasonable and prudent manner for an ITM Program loan;

(5) Failure within the time period specified to correct an underwriting, closing, disbursing, servicing, liquidation, litigation, or reporting deficiency, or failure in any material respect to take other corrective action, after receiving notice from EDA of a deficiency and the need to take corrective action;

(6) Engaging in a pattern of uncooperative behavior or taking an action that EDA determines is detrimental to an EDA program, that undermines management or administration of a program, or that is not consistent with standards of good conduct. Prior to issuing a notice of a proposed enforcement action or immediate suspension under § 311.1101 based upon this paragraph, EDA must send prior written notice to the Lender explaining why the lender's actions were uncooperative, detrimental to the program, undermined EDA's management of the program, or were not consistent with standards of good conduct. The prior notice must also state that the lender's actions could give rise to a specified enforcement action, and provide the Lender with a reasonable time to cure the deficiency before any further action is taken;

(7) Repeated failure to correct continuing deficiencies;

(8) Unauthorized disclosure of reports, any ratings assigned to the lender by EDA, or confidential information;

(9) Indictment on felony or fraud charges of an officer, or loan agent involved with ITM Program loans for the lender;

(10) As otherwise authorized by law;

(11) Upon a determination by EDA that one or more of the grounds in paragraph (c) of this section, as applicable, exist and that immediate action is needed to prevent significant impairment of the integrity of the ITM Program;

(12) Upon a determination by EDA that one or more of the grounds in paragraph (c) of this section exists and that immediate action is needed to prevent significant impairment of the integrity of the ITM Program; and

(13) Any other reason that EDA determines may increase EDA's financial risk.

(d) *Grounds required for certain enforcement actions against lenders.* The grounds that are required to take enforcement action are:

(1) *For ITM Program suspensions and revocations*—

(i) False statements knowingly made in any required written submission to EDA; or

(ii) An omission of a material fact from any written submission required by EDA; or

(iii) A willful or repeated violation of EDA regulations; or

(iv) A willful or repeated violation of any condition imposed by EDA with respect to any application, request, or agreement with EDA; or

(v) A violation of any cease and desist order of EDA.

(2) *For ITM Program immediate suspension*—EDA may suspend a lender, effective immediately, if in addition to meeting the grounds set forth in paragraph (d)(1) of this section, the Assistant Secretary finds extraordinary circumstances requiring immediate action in order to protect the financial or legal position of the United States.

(3) *For cease and desist orders*—

(i) A violation of EDA regulations, or

(ii) Where a lender is or is about to engage in any acts or practices that will violate EDA's regulations.

(4) *For an emergency cease and desist order*—

(i) Where grounds for cease and desist order are met,

(ii) The Assistant Secretary finds extraordinary circumstances, and

(iii) EDA must act expeditiously to protect the financial or legal position of the United States.

(5) *For transfer of loan portfolio*—

(i) Where a court has appointed a receiver; or

(ii) The lender is either not in compliance with capital requirements or is insolvent. A lender is insolvent within the meaning of this provision when all of its capital, surplus, and undivided profits are absorbed in funding losses and the remaining assets are not sufficient to pay and discharge its contracts, debts, and other obligations as they come due.

(6) *For transfer of servicing activity*—

(i) Where grounds for transfer of loan portfolio are met; or

(ii) Where the lender is otherwise operating in an unsafe and unsound condition.

§ 311.1101 Types of enforcement actions—lenders.

Upon a determination that the grounds set forth in § 311.110 exist, EDA may undertake, in its discretion, one or more of the following enforcement actions for each of the types of lenders listed. EDA will take such action in accordance with procedures set forth in § 311.1102. If enforcement action is taken under this section and the lender fails to implement required corrective action in any material respect within the required timeframe in response to the enforcement action, EDA may take further enforcement action, as authorized by law. EDA's decision to take an enforcement action will not, by itself, invalidate a guarantee previously provided by EDA.

(a) *Enforcement actions against lenders*—(1) *Imposition of portfolio guarantee dollar limit.* EDA may limit the maximum dollar amount that EDA will guarantee on the lender's ITM Program loans.

(2) *Suspension or revocation from EDA program.* EDA may suspend or revoke a lender's authority to participate in the ITM Program, including the authority to make, service, liquidate, or litigate ITM Program loans. Section 311.1100(d)(1) sets forth the grounds for EDA program suspension or revocation of a lender.

(3) *Immediate suspension.* EDA may suspend, effective immediately, a lender's authority to participate in the ITM Program, or the authority to make, service, liquidate, or litigate ITM Program loans. Section 311.1100(d)(2) sets forth both the grounds for immediate suspension of delegated authority for all lenders and grounds for immediate suspension of a lender.

(4) *Debarment.* In accordance with 2 CFR parts 180 and 2700, EDA may take any necessary action to debar a person, as defined in § 311.3, including but not limited to an officer, a director, a general partner, a manager, an

employee, an agent, or other participant in the affairs of a lender's ITM Program-related operations.

(5) *Other actions available under law.* EDA may take all other enforcement actions against lenders available under law.

(b) *Enforcement actions specific to lenders.* In addition to those enforcement actions listed in paragraph (a) of this section, EDA may take any one or more of the following enforcement actions specific to lenders:

(1) *Cease and desist order.* EDA may issue a cease and desist order against the lender. The cease and desist order may either require the lender to take a specific action, or to refrain from a specific action. The cease and desist order may be issued as effective immediately (or as a proposal for order).

(2) *Prohibited actions.* EDA may prohibit a management official from participating in management of the ITM Program loan or from reviewing, approving, closing, servicing, liquidating or litigating any ITM Program loan, or any other activities of the lender while the removal proceeding is pending in order to protect a lender or the interests of EDA.

(3) *Initiate request for appointment of receiver.* EDA may make application to a district court to take exclusive jurisdiction of a lender and appoint a trustee or receiver to hold or administer the portfolio of ITM Program loans and sell such loans to a third party, and/or take possession of servicing activities of ITM Program loans and sell such servicing rights to a third party.

(4) *Civil monetary penalties for report filing failure.* EDA may seek civil penalties of not more than $5,000 a day against a lender that fails to file any regular or special report by its due date as specified by regulation or EDA written directive.

§ 311.1102 General procedures for enforcement actions against lenders.

(a) *In general.* Except as otherwise set forth for the enforcement actions listed in paragraphs (b) and (c) of this section, EDA will follow the procedures listed below.

(1) *EDA's notice of enforcement action.* (i) When undertaking an immediate suspension under § 311.1101 or prior to undertaking an enforcement action set forth in § 311.1101, EDA will issue a written notice to the affected lender identifying the proposed enforcement action or notifying it of an immediate suspension. The notice will set forth in reasonable detail the underlying facts and reasons for the proposed action or immediate suspension. If the notice is for a proposed or immediate suspension, EDA will also state the scope and term of the proposed or immediate suspension.

(ii) If a proposed enforcement action or immediate suspension is based upon information obtained from a third party other than the lender, EDA's notice of proposed action or immediate suspension will provide copies of documentation received from such third party, or the name of the third party in case of oral information, unless EDA determines that there are compelling reasons not to provide such information. If compelling reasons exist, EDA will provide a summary of the information it received to the lender.

(2) *Lender's opportunity to object.* (i) A lender that desires to contest a proposed enforcement action or an immediate suspension must file, within 30 calendar days of its receipt of the notice or within some other term established by EDA in its notice, a written appeal to the appropriate EDA official identified in the notice. Notice will be presumed to have been received within five calendar days of the date of the notice unless the Lender can provide compelling evidence to the contrary.

(ii) The lender's appeal must set forth in detail all grounds known to the Lender to contest the proposed action or immediate suspension and all mitigating factors, and must include documentation that the lender believes is most supportive of its appeal. A lender must exhaust this administrative remedy in order to preserve its appeal to a proposed enforcement action or an immediate suspension.

(iii) If a lender can reasonably demonstrate, as determined by EDA, that the lender does not understand the justification given by EDA in its notice of the action, the agency will provide clarification. EDA will provide the requested clarification in writing to the lender or notify the lender in writing that EDA has determined that such clarification is not necessary. EDA, in its sole discretion, will further advise in writing whether the lender may have additional time to present its appeal to the notice. Requests for clarification must be made to the appropriate EDA official identified in the notice in writing and received by EDA within the 30 calendar day timeframe or the timeframe given by the notice for response.

(iv) A lender may request additional time to respond to EDA's notice if it can show that there are compelling reasons why it is not able to respond within the 30-day timeframe or the response timeframe given by the notice. If such requests are submitted to the agency, EDA may, in its sole discretion, provide the requesting lender with additional time to respond to the notice of proposed action or immediate suspension. Requests for additional time to respond must be made in writing to the appropriate EDA official identified in the notice and received by EDA within the 30 calendar day timeframe or the response timeframe given by the notice.

(v) Prior to the issuance of a final decision by EDA, if a lender can show that there is newly discovered material evidence that, despite the lender's exercise of due diligence, could not have been discovered within the timeframe given by EDA to respond to a notice, or that there are compelling reasons beyond the lender's control as to why it was not able to present a material fact or argument to EDA, and that the lender has been prejudiced by not being able to present such information, the lender may submit such information to EDA and request that the Agency consider such information in its final decision.

(3) *EDA's notice of final agency decision where lender filed appealed the proposed action or immediate suspension.*

(i) If the affected lender timely appeals a proposed enforcement action other than an immediate suspension in accordance with this section, EDA must issue a written notice of final decision to the affected lender advising whether EDA is undertaking the proposed enforcement action and setting forth the grounds for the decision. EDA will issue such a notice of decision within 90 calendar days of either receiving the appeal or from when additional information is provided under paragraph (a)(2)(v) or (a)(3)(iii) of this section, whichever is later, unless EDA provides notice that it requires additional time.

(ii) If the affected lender timely appeals a notice of immediate suspension, EDA must issue a written notice of final decision to the affected lender within 30 calendar days of receiving the appeal advising whether EDA is continuing with the immediate suspension, unless EDA provides notice that it requires additional time. If the lender submits additional information to EDA (under paragraph (a)(2)(v) or (a)(3)(iii) of this section) after submitting its appeal but before EDA issues its final decision, EDA must issue its final decision within 30 calendar days of receiving such information, unless EDA provides notice that it requires additional time.

(iii) Prior to issuing a notice of decision, EDA may request additional information from the affected lender or other parties and conduct any other investigation it deems appropriate. If EDA determines, in its sole discretion, to consider an untimely appeal, it must issue a notice of final decision pursuant to this paragraph (a)(3).

(4) *EDA's notice of final agency decision where no appeal was filed or an untimely appeal was not considered.* If EDA chooses not to consider an untimely appeal or if the affected lender fails to file a written appeal to a proposed enforcement action or an immediate suspension, and if EDA continues to believe that such proposed enforcement action or immediate suspension is appropriate, EDA must issue a written notice of final decision to the affected lender that EDA is undertaking one or more of the proposed enforcement actions against the lender or that an immediate suspension of the lender will continue. Such a notice of final decision need not state any grounds for the action other than to reference the lender's failure to file a timely appeal, and represents the final agency decision.

(5) *Appeals.* A lender may appeal the final agency decision only in the appropriate Federal District Court.

Dated: August 30, 2016.

Roy K.J. Williams,

Assistant Secretary of Commerce for Economic Development.

[FR Doc. 2016–22284 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–24–P

DEPARTMENT OF COMMERCE

Economic Development Administration

13 CFR Part 312

[Docket No.: 160615526–6526–01]

RIN 0610–AA68

Regional Innovation Program

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice of proposed rulemaking; request for public comment.

SUMMARY: Through this notice of proposed rulemaking ("NPRM"), the Economic Development Administration ("EDA" or "the Agency"), U.S. Department of Commerce ("DOC"), proposes and requests comments on the Agency's implementation of the Regional Innovation Program as authorized by section 27 of the Stevenson-Wydler Technology Innovation Act of 1980, as amended ("Stevenson-Wydler" or the "Act"). Through the Regional Innovation Strategies Program ("RIS Program"), the centerpiece of the Regional Innovation Program, EDA currently awards grants for capacity-building programs that provide proof-of-concept and commercialization assistance to innovators and entrepreneurs and for operational support for organizations that provide essential early-stage funding to startup companies. This NPRM, for the first time, lays out the overarching regulatory framework for the Regional Innovation Program and specifically focuses on outlining the structure of the RIS Program.

DATES: Written comments on this NPRM must be submitted by November 21, 2016.

ADDRESSES: Comments on the NPRM may be submitted through any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. EDA will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).
- *Email: regulations@eda.gov.* Include "Comments on EDA's Regional Innovation Program regulations" and Docket No. 160615526–6526–01 in the subject line of the message.
- *Fax:* (202) 482–5671. Please indicate "Attention: Office of the Chief Counsel; Comments on EDA's Regional Innovation Program regulations" and Docket No. 160615526–6526–01 on the cover page.
- *Mail:* Economic Development Administration, Office of the Chief Counsel, U.S. Department of Commerce, 1401 Constitution Avenue NW., Suite 72023, Washington, DC 20230. Please indicate "Comments on EDA's Regional Innovation Program regulations" and Docket No. 160615526–6526–01 on the envelope.

All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible.

FOR FURTHER INFORMATION CONTACT: Mara Quintero Campbell, Regional Counsel, Office of the Chief Counsel, Economic Development Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Suite 72023, Washington, DC 20230; telephone: (202) 482–9055.

SUPPLEMENTARY INFORMATION:

Background on Regional Innovation Program

History

In recent years, concerns about America's global competitiveness led to calls for the Federal Government to more actively foster innovation and better coordinate Federal support for scientific and technological research and development, technology transfer, and commercialization. In particular, without Federal support, local communities struggled to effectively support the development of regional innovation clusters (defined below), which research has shown to be a significant catalyst of economic development. At the same time, regional innovation was hampered by limited access to the capital necessary to implement the innovative manufacturing technologies required to compete in the twenty-first century global economy.

In response to these concerns and with a desire to maintain America's role as a leader in innovation, Congress enacted section 27 of Stevenson-Wydler ("section 27" or "Regional Innovation Program") as part of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Reauthorization Act of 2010, Public Law 111–358 (Jan. 5, 2010) ("COMPETES Act"). As originally enacted by Congress, section 27 authorized the Secretary of Commerce ("Secretary") to "establish a regional innovation program to encourage and support the development of regional innovation strategies, including regional innovation clusters and science and research parks." In 2014, Congress enacted legislation that narrowed the scope of the Regional Innovation Program. *See* Public Law 113–235 (Dec. 16, 2014). This legislative change is discussed more fully below. The Regional Innovation Program now encompasses two complementary sub-programs: the Regional Innovation Strategies Program ("RIS Program") set forth in section 27(b) of the Act, and the Regional Innovation Research and Information Program ("RIRI Program") set forth in section 27(c) of the Act.

Given EDA's leadership in and support of innovation and entrepreneurship as key elements of a robust economy, the Secretary turned to EDA to develop and implement the Regional Innovation Program. Established under the Public Works and Economic Development Act of 1965, as amended (42 U.S.C. 3121 *et seq.*) ("PWEDA"), EDA leads the Federal economic development agenda by promoting innovation and competitiveness, preparing American regions for growth and success in the worldwide economy. EDA makes investments to facilitate job creation for U.S. workers, increase private-sector investment, promote American innovation, and accelerate long-term sustainable economic growth. EDA's regulations, codified at 13 CFR parts 300 through 315, provide the framework through which the Agency administers its economic development assistance programs.

Structure

Through the RIS Program (section 27(b) of Stevenson-Wydler), the core of the Regional Innovation Program, EDA competitively awards grants to eligible applicants for activities related to the formation and development of regional innovation clusters. 15 U.S.C. 3722(b). Stevenson-Wydler defines a regional innovation cluster as "a geographically bounded network of similar, synergistic, or complementary entities that—(A) are engaged in or with a particular industry sector and its related sectors; (B) have active channels for business transactions and communication; (C) share specialized infrastructure, labor markets, and services; and (D) leverage the region's unique competitive strengths to stimulate innovation and create jobs." 15 U.S.C. 3722(f)(1). The RIRI Program (section 27(c) of Stevenson-Wydler) is designed to formulate and disseminate best practices for regional innovation strategies, provide technical assistance for the development and implementation of regional innovation strategies, support the development of metrics to evaluate regional innovation strategies, collect and publicize data on regional innovation cluster activity in the United States, and fund competitive research grants to support the goals of the RIRI Program. This NPRM focuses on the RIS Program because EDA has not yet implemented the RIRI Program. However, these proposed regulations—and, in particular, the definition sections—are structured to incorporate the RIRI Program into a future subpart C of part 312 of title 13 of the Code of Federal Regulations once EDA implements the RIRI Program. In addition to awarding grants under the RIS and RIRI Programs, EDA anticipates at a future date conducting COMPETES Act prize competitions that support the goals and objectives of the Regional Innovation Program. *See* 15 U.S.C. 3719.

EDA's economic development assistance programs under PWEDA and the RIS Program seek to increase economic growth and resilience, enhance prosperity, and improve quality of life, but they approach the goal from different angles, as reflected in the enabling statutes and regulations. For example, the focus of PWEDA's core programs is increasing employment and private investment in economically distressed regions. Funding generally is limited to regions that meet chronic high unemployment or low per capita income criteria, and grant rates increase with the level of economic distress up to a maximum of 100 percent in limited circumstances. Conversely, the RIS Program focuses on encouraging scientific and technological innovation and collaboration; it thus provides funding to a broader range of entities and does not require applicants to demonstrate economic distress. Moreover, it also is capped at a 50 percent grant rate.

Implementation

EDA publicly launched the RIS Program in September 2014 when it announced the first round of competitions for funding under the Program. The announcement of a Federal Funding Opportunity ("FFO") identified three separate competitions for a total of $15 million in Federal funding: the i6 Challenge, Science and Research Park Development Grants, and Seed Fund Support ("SFS") Grants (formerly known as Cluster Grants for Seed Capital Funds). The i6 Challenge, first launched in 2010 as part of the multi-agency Startup America Initiative, is designed to support the creation of programs for innovation and entrepreneurship—specifically, the development, creation, or expansion of proof-of-concept and commercialization programs that increase the development of innovations, ideas, intellectual property, and research into viable companies. Science and Research Park Development Grants supported feasibility and planning studies to create innovation hubs for driving the results of applied research and development to the commercial marketplace by supporting the entire product or process lifecycle from idea generation to business creation.

SFS Grants support activities related to the feasibility, planning, formation, launch, or expansion of cluster-based seed capital funds to assist innovation-based startups with high growth potential. After considering more than 240 applications, in early 2015, EDA awarded 17 i6 Grants, 12 Science and Research Park Development Grants, and 9 SFS Grants to applicants throughout EDA's six regions.

In 2014, Congress amended the Regional Innovation Program in section 705 of the Revitalize American Manufacturing and Innovation Act of 2014, Public Law 113–235 (Dec. 16, 2014) ("RAMI"). Under RAMI, Congress eliminated the provisions authorizing Science and Research Park Development Grants and Loan Guarantees for Science Park Infrastructure but did maintain eligibility for such parks to apply for RIS awards. Accordingly, when EDA announced a second round of RIS Program competitions in August 2015, it included $10 million in Federal funding for i6 Challenge Grants and SFS Grants, and no longer had a separate Science and Research Park Development Grant competition. In addition, consistent with changes made by Congress in RAMI to section 27(b)(7) of the Act, EDA implemented a targeted outreach program to ensure that public and private sector entities in rural communities were aware of the opportunity. After considering 168 applications for funding, EDA awarded 17 i6 Grants and 8 SFS Grants in early 2016.

A third round of competitions for $15 million in funding for i6 Challenge Grants and SFS Grants was announced in April 2016.

With EDA's RIS funding, successful applicants have undertaken transformative projects such as the development of a hardware entrepreneurship ecosystem, expansion of a seed capital fund focused on commercializing water technology, and investigation of the feasibility of constructing a test track for connected and autonomous vehicles. Grant recipients are required to provide semi-annual reports, using EDA-developed metrics that are consistent across grantees, that EDA uses to evaluate the impact of the RIS Program.

Administration

Administration and management of the Regional Innovation Program is an EDA-wide responsibility. The Regional Innovation Program (including the RIS Program) is broadly overseen by the Office of Innovation and Entrepreneurship ("OIE"), which was established by the Secretary pursuant to section 25(c) of the Act. Housed within EDA, OIE works to foster a more innovative U.S. economy focused on turning new ideas and inventions into products and technologies that spur job growth and competitiveness while promoting economic development through innovation and entrepreneurship. In addition, EDA's Deputy Assistant Secretary for Regional Affairs has served as the Grants Officer for RIS Program awards, with day-to-day administration of these awards being handled by the Agency's regional offices.

Because of significant differences in EDA's authority under PWEDA and Stevenson-Wydler, EDA is proposing regulations specific to the Regional Innovation Program. This NPRM focuses on the RIS Program, the only portion of the Regional Innovation Program currently being implemented in these proposed regulations. The basic regulatory framework proposed for this program is summarized below.

Section-by-Section Analysis

Section 312.1—Purpose and Scope of the Regional Innovation Program

This section sets forth the general purpose of the Regional Innovation Program and provides a brief description of its two sub-programs (*i.e.*, RIS and RIRI Programs). 15 U.S.C. 3722(b), (c). Section 312.1 also informs the public that the Secretary has delegated to EDA the authority to implement and administer the Regional Innovation Program.

Section 312.2—General Definitions From Public Works and Economic Development Act Regulations Inapplicable to This Part

This section establishes that the definitions of § 300.3 of chapter III are not applicable to the Regional Innovation Program. Section 300.3 defines terms related to EDA's administration of grant programs authorized by PWEDA. The Regional Innovation Program was established by Stevenson-Wydler, with distinct programmatic and eligibility criteria. Therefore, EDA proposes to include an umbrella Regional Innovation Program definition section that applies to all of part 312 and a separate definition section that applies only to the RIS Program, as described in §§ 312.3 and 312.5 respectively, below.

Section 312.3—General Definitions

This section defines terms applicable to the Regional Innovation Program. The definitions are applicable to the RIS Program as well as the RIRI Program.

Section 312.3 includes terms defined in the Act relevant to the Regional Innovation Program such as *Eligible recipient, Federal agency, Federal laboratory, Regional innovation clusters, Secretary,* and *State.*

This section also includes terms that EDA has previously defined and regularly uses in all of its grant programs, such as *In-kind contribution(s)* and *Recipient.* Many of these terms have been adopted almost verbatim from the PWEDA definitions at §§ 300.3 and 314.1 of chapter III; however, the terms *FFO, Grant, Investment rate, Project, Real property,* and *Region* have been slightly modified to reference Stevenson-Wydler as opposed to PWEDA, or to increase readability.

EDA also proposes to adopt the commonly used definitions for the terms *Equipment, Federal interest,* and *Nonprofit organization* from the Federal Uniform Administrative Requirements and Cost Principles as set out in 2 CFR part 200 ("Uniform Guidance"). *See* 200 CFR 200.33, 200.41, and 200.70.

In addition, EDA establishes new definitions for the terms *Economic Development Organization, Public-private partnership,* and *Science or research park* because they are *Eligible recipients* under the RIS program. *See* 15 U.S.C. 3722(b)(3). Finally, EDA also establishes new definitions for Regional Innovation Program, RIS Program, and RIRI Program.

Section 312.4—Purpose and Scope of the Regional Innovation Strategies Program

This section sets forth the general purpose and scope of the RIS Program as identified in section 27(b) of the Act. 15 U.S.C. 3722(b). Under the RIS Program, EDA will award competitive grants to eligible applicants that build public and private capacity to invent, improve, and commercialize new products and services with the goal of promoting economic growth in the United States.

Section 312.5—Regional Innovation Strategies Program Definitions

This section sets forth the definition of *Institution of higher education* ("*IHE*"), a term that has a meaning unique to the RIS Program. Under the Act, both for-profit and nonprofit IHEs are eligible recipients under the RIS Program. 15 U.S.C. 3722(b)(3)(D). *See* analysis of § 312.6, below. This means that the RIS Program cannot use the standard definition of IHE promulgated by the U.S. Department of Education ("ED") in 20 U.S.C. 1001 and adopted in the Uniform Guidance at 2 CFR 200.55 because that definition includes conditions that the IHE be "public" or "nonprofit." However, since the ED definition is the standard Government-wide definition, EDA proposes to incorporate as much of the ED definition as possible while omitting language related to "public" or "nonprofit" that conflicts with section 27(b) of the Act. Thus, in EDA's definition of IHE in § 312.5, EDA has duplicated 20 U.S.C. 1001 but with the following deletions: (1) paragraph (4) of 20 U.S.C. 1001(a) that requires an IHE to be "a public or other nonprofit institution"; (2) a cross-reference to paragraph (4) of 20 U.S.C. 1001(a) that appeared in 20 U.S.C. 1001(b)(1); and (3) the reference in 20 U.S.C. 1001(b)(2) to "public or nonprofit private".

Section 312.6—Eligible Recipients

This section identifies those entities eligible to apply for and potentially receive funding under the RIS Program. The list is derived from the definition of "*Eligible recipient*" in section 27(b)(3) with one proposed clarification. Paragraph (D) of section 27(b)(3) of the Act lists and groups together several types of entities. 15 U.S.C. 3722(b)(3)(D). EDA proposes to separate nonprofit organizations from the other entities to provide needed clarity. Section 27(b)(3)(D)(i) permits grants to for-profit as well as nonprofit institutions of higher education, public-private partnerships, science or research parks, Federal laboratories, and economic development organizations or similar entities. Congress established "nonprofit organizations" as a separate type of entity eligible for an RIS award and did not include the term "nonprofit" as a modifier on the other types of entities that are eligible recipients. Grouping together all of these various types of entities could lead to confusion that "nonprofit" applies to institutions of higher education, public-private partnerships, science or research parks, federal laboratories, and economic development organizations or similar entities, when it does not.

Both nonprofit organizations and the other entities listed in section 27(b)(3)(D) must still meet the additional eligibility requirement in section 27(b)(3)(D)(ii) of demonstrating that a State or a political subdivision of a State supports the application.

Consistent with section 27(b), individuals are not eligible recipients.

Section 312.7—Eligible Project Activities

This section identifies the project activities that are eligible for potential funding under the RIS Program. The list is derived from section 27(b)(2) with proposed modifications to include three additional eligible activities and four activities that EDA proposes should be ineligible. 15 U.S.C. 3722(b)(2). The list of eligible activities provided by Congress is non-exhaustive because section 27(b)(2) expressly allows discretion for the Secretary to determine appropriate RIS Program activities. EDA therefore has added a catchall to the end of the list of eligible activities that provides "(11) Any other activity determined appropriate by the Assistant Secretary." To that list, EDA also proposes to add two further activities, "(9) Purchase of equipment, but only to the extent that such equipment is used to support another eligible activity as described in this section (the recipient may be required to secure and record the Federal interest in the equipment)" and "(10) Modifications or renovations of a facility that are necessary to install equipment."

With respect to (9) above, at times new innovations require the use of technologies, such as a three-dimensional printer, not readily available to an applicant. As such, EDA proposes to permit the purchase of equipment in limited circumstances. However, because EDA does not believe Congress intended for the RIS Program to primarily fund equipment, EDA proposes to confine the purchase of equipment to only those purchases that are otherwise used to support another eligible project activity described in § 312.7. To protect the Federal interest in such equipment, EDA may require eligible recipients that purchase equipment to provide EDA with a security interest in the equipment that is perfected and placed of record consistent with applicable law (for example, through the execution of a Uniform Commercial Code Financing Statement (UCC–1) or other statement acceptable in form and substance to EDA).

As a natural extension of including the purchase of equipment as an eligible project activity in § 312.7(a)(9), there are situations when installing the equipment may require some minor modifications or renovations to a facility and this proposed rule makes those activities eligible as well in § 312.7(a)(10).

On the other hand, EDA proposes to make expenses related to construction (other than minor modifications or renovations of a facility needed to install equipment) and acquisition or improvement of real property ineligible activities. While EDA acknowledges that at times constructing a new facility and/or purchasing real property may support the development of regional innovation clusters, EDA does not believe those specific activities are within the core purposes of the RIS Program as defined by Congress. It is clear that Congress's intent for the RIS Program is to promote actual innovation, not the facilities or places where such activities may take place. There are other grant programs throughout the Federal Government that fund these activities (*e.g.,* PWEDA). Further, as a practical matter, the costs associated with construction and real property acquisition or improvements are more substantial than the other types of eligible activities identified in § 312.7 and consequently, permitting such activities would diminish EDA's ability to award as many grants as possible with its limited appropriations.

EDA also proposes to make ineligible the use of RIS Program or matching share funds for equity investments. RIS Program awards have supported the creation of mechanisms for attracting, gathering, and deploying investment capital within regional innovation clusters that fill regional gaps in funding for early-stage companies, but RIS Program funds cannot be used to make those investments themselves. Further, there are other grant programs throughout the Federal Government that fund these activities such as the Small Business Administration's Small Business Investment Company program.

Finally, EDA proposes that lending programs such as providing direct loans or capitalizing a revolving loan fund be ineligible. Providing loans, or permitting grant funds to support lending programs, requires specific Congressional authorization that is not provided in section 27 of the Act.

Section 312.8—Investment Rates

This section identifies that the maximum grant rate permitted under section 27(b)(6) of the Act is 50 percent and states that there is no minimum grant rate. 15 U.S.C. 3722(b)(6). The grant rate here represents the percentage of the total Project cost that can be funded with EDA funds.

Section 312.9—Matching Share Requirements

This section clarifies that an applicant's matching share requirements may be met by either cash or in-kind contribution(s). Matching share is the difference between the amount of the EDA investment permitted by the Act (*see* § 312.8), and the total eligible costs of a proposed project. Consistent with EDA's regulations for programs authorized by PWEDA at 13 CFR 301.5, this proposed rule requires an applicant to demonstrate, at the time of application, that matching share is committed to the project, will be available as needed, and is not or will not be conditioned in any way that would conflict with the requirements of the RIS Program.

EDA expressly retains discretion to determine whether the matching share is adequately documented to ensure that awards comply with the statutorily-established maximum investment rate. Applicants must comply with their own rules (as established in statutes, ordinances, bylaws, or the like) for appropriating or committing organizational funds; in many cases, these rules authorize the organization's governing body (rather than an individual executive) to approve proposed expenditures of cash but permit executives to commit in-kind personnel time based on their authority to manage employees and their workload. Applicants should consult their governance documents for guidance.

Section 312.10—Application Components

This section sets forth the minimum information that applicants must provide to EDA to be considered for an RIS Program award, as outlined in section 27(b)(4)(B). 15 U.S.C. 3722(b)(4)(B). This includes information necessary for EDA to identify how the proposed activity will support an existing, or further develop an emerging, regional innovation cluster; how much outside support the cluster will receive; the methodology the applicant will use to get other entities to participate in and benefit from the cluster; the extent to which the cluster will stimulate innovation and positively affect the region's economy; the capacity for applicants to access or contribute to a well-trained workforce; the ability of the recipient to attract additional funds; and the sustainability of the activity. To ensure that requirements remain current, EDA will specify application procedures and materials (such as required standard Federal forms) in each FFO for the RIS Program.

Section 312.11—Application Evaluation and Selection Criteria

This section provides notice that EDA will evaluate and select complete applications based on the priorities and requirements set forth in section 27(b), the evaluation criteria and funding priorities identified in the FFO announcement, available funds, competitiveness of the application, and compliance with any other applicable Federal statutes and regulations. EDA proposes this flexible structure to ensure that the agency complies with required statutory elements such as "special considerations" for certain applicants "from regions that contain communities negatively impacted by trade" or who agree "to collaborate with local workforce investment area boards" and at the same time follows Congressional directives outlined in EDA's annual appropriation and supports Administration priorities. 15 U.S.C. 3722(b)(4)(C), (b)(5); *see, e.g.,* H.R. Rep. 114–130 at 7 (May 27, 2015).

The section also sets forth that EDA will notify applicants as soon as practicable regarding whether their applications are selected for funding and provides notice that there is no appeal process for denied applications.

Section 312.12—General Terms and Conditions for Investment Assistance

This section expressly provides that most of the general terms and conditions found in part 302 of title 13 of the Code of Federal Regulations apply to the RIS Program. These terms and conditions either apply Government-wide as mandated by statute or regulation, or are EDA-specific requirements and typically apply to all EDA grant programs, such as those authorized by PWEDA. EDA proposes to exclude those specific paragraphs of part 302 that are irrelevant to the RIS or RIRI Programs, or are unique to PWEDA. The excluded requirements are those related to "Procedures in disaster areas" (§ 302.2); "Project servicing for loans, loan guarantees and Investment Assistance" (§ 302.3); "Inter-governmental review of projects" (§ 302.9); and "Attorneys' and consultants' fees, employment of expediters, and post-employment restriction" (§ 302.10).

Classification

Prior notice and opportunity for public comment are not required for rules concerning public property, loans, grants, benefits, and contracts. 5 U.S.C. 553(a)(2). Because prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis has not been prepared.

Executive Orders No. 12866 and 13563

This proposed rule was drafted in accordance with Executive Orders 12866 and 13563. It was reviewed by the Office of Management and Budget ("OMB"), which found that the proposed rule will be a "significant regulatory action" as defined by Executive Orders 12866 and 13563.

Congressional Review Act

This proposed rule is not major under the Congressional Review Act (5 U.S.C. 801 *et seq.*).

Executive Order No. 13132

Executive Order 13132 requires agencies to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in Executive Order 13132 to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." It has been determined that this proposed rule does not contain policies that have federalism implications.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) ("PRA") requires that a Federal agency consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the PRA unless that collection displays a currently valid OMB Control Number. It has been determined that the PRA does not apply to the proposed rule because the rule does not collect any new information requiring OMB approval. The proposed rule will use the previously approved Standard Form 424 family of forms to collect information relevant to the grant applications.

The following table provides a complete list of the collections of information (and corresponding OMB Control Numbers) set forth in this proposed rule. These collections of information are necessary for the proper performance and functions of EDA.

Part or section of this proposed rule	Nature of request	Form/title/OMB control no.
312.10	All Eligible Applicants must submit required application materials using the Standard Form 424 family of forms.	SF–424 (4040–0004), SF–424A (4040–0006), SF–424B (4040–0007).

List of Subjects in 13 CFR Part 312

Application requirements, Cluster grants, Financial assistance, Regional innovation, Regional innovation clusters, Regional Innovation Program, Regional Innovation Research and Information Program, Regional Innovation Strategies Program, Research.

Regulatory Text

For the reasons set forth in the preamble, EDA proposes to amend title 13, chapter III of the Code of Federal Regulations by adding part 312 to read as follows:

PART 312—REGIONAL INNOVATION PROGRAM

Subpart A—General Provisions

Sec.
312.1 Purpose and scope of the Regional Innovation Program.
312.2 General definitions from Public Works and Economic Development Act regulations inapplicable to this part.
312.3 General definitions.

Subpart B—Regional Innovation Strategies Program

312.4 Purpose and scope of the Regional Innovation Strategies Program.
312.5 Regional Innovation Strategies Program definitions.
312.6 Eligible recipients.
312.7 Eligible project activities.
312.8 Investment rates.
312.9 Matching share requirements.
312.10 Application components.
312.11 Application evaluation and selection criteria.
312.12 General terms and conditions for investment assistance.

Subpart C—Regional Innovation Research and Information Program

312.13 through 312.17 [Reserved]

Authority: 15 U.S.C. 3701 *et seq.;* Department of Commerce Organization Order 10–4.

Subpart A—General Provisions.

§ 312.1 Purpose and scope of the Regional Innovation Program.

The purpose of the Regional Innovation Program is to encourage and support the development of regional innovation strategies. The Regional Innovation Program includes two sub-programs. One is focused on the formation and development of regional innovation clusters and implemented through the Regional Innovation Strategies Program. 15 U.S.C. 3722(b). The second program is focused on best practices, metrics and the collection and dissemination of information related to regional innovation strategies, achieved through the Regional Innovation Research and Information Program. 15 U.S.C. 3722(c). The Secretary has delegated to the Economic Development Administration the authority to implement and administer the Regional Innovation Program.

§ 312.2 General definitions from Public Works and Economic Development Act regulations inapplicable to this part.

The definitions contained in § 300.3 of this chapter do not apply to this part.

§ 312.3 General definitions.

As used in this part, the following terms shall have the following meanings:

Act or *Stevenson-Wydler* means the Stevenson-Wydler Technology Innovation Act of 1980, as amended (15 U.S.C. 3701 *et seq.*).

Assistant Secretary means the Assistant Secretary of Commerce for Economic Development within the Department.

Department of Commerce, Department, or *DOC* means the U.S. Department of Commerce.

Economic Development Organization means an organization whose primary purpose is to support the economic development of a community or region.

EDA means the Economic Development Administration within the Department.

Eligible applicant means an entity qualified to be an eligible recipient or its authorized representative.

Eligible recipient means a recipient that meets the requirements of § 312.6.

Equipment is defined at 2 CFR 200.33.

Federal agency means any executive agency as defined in 5 U.S.C. 105, and the military departments as defined in 5 U.S.C. 102, as well as any agency of the legislative branch of the Federal Government.

Federal funding opportunity or *FFO* means an announcement that EDA publishes during the fiscal year on a Federal Government grants platform or on EDA's Internet Web site at *http://www.eda.gov, https://www.eda.gov/oie/,* or any successor Web site, that provides the funding amounts, application and programmatic requirements, funding priorities, special circumstances, and other information concerning a specific competitive solicitation under EDA's Regional Innovation Program.

Federal interest is defined at 2 CFR 200.41, in accordance with 2 CFR 200.316.

Federal laboratory means any laboratory, any federally funded research and development center, or any center established under section 7 or section 9 of the Act that is owned, leased, or otherwise used by a Federal agency and funded by the Federal Government, whether operated by the government or by a contractor.

Grant means the financial assistance award of EDA funds to an eligible recipient, under which the Eligible Recipient bears responsibility for meeting a purpose or carrying out an activity authorized under Stevenson-Wydler. *See* 31 U.S.C. 6304.

In-kind contribution(s) means non-cash contributions, which may include contributions of space, Equipment, services, and assumptions of debt that are fairly evaluated by EDA and that satisfy applicable Federal Uniform Administrative Requirements and Cost Principles as set out in 2 CFR part 200.

Indian tribe means an entity on the list of recognized tribes published pursuant to the Federally Recognized Indian Tribe List Act of 1994, as amended (Pub. L. 103–454) (25 U.S.C. 479a *et seq.*), and any Alaska Native village or Regional Corporation (as defined in or established under the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*)). This term includes the governing body of an Indian tribe, nonprofit Indian corporation (restricted to Indians), Indian authority, or other nonprofit Indian tribal organization or entity; provided that the Indian tribal organization or entity is wholly owned by, and established for the benefit of, the Indian tribe or Alaska Native village.

Investment or *Investment assistance* means a grant entered into by EDA and a recipient.

Investment rate means, as set forth in § 312.8 of this part, the amount of the EDA investment in a particular project expressed as a percentage of the total project cost.

Matching share or *Local share* means the non-EDA funds and any in-kind contribution(s) that are approved by EDA and provided by a recipient or third party as a condition of an investment. The matching share may include funds from another Federal agency only if authorized by a statute that allows such use, which may be determined by EDA's reasonable interpretation of such authority.

Nonprofit organization is defined at 2 CFR 200.70.

Office of Innovation and Entrepreneurship or *OIE* means the office established by 15 U.S.C. 3720.

Project means the proposed or authorized activity (or activities), the purpose of which fulfills EDA's mission and program requirements as set forth in the Act and this part, and which may be funded in whole or in part by EDA investment assistance.

Public-private partnership means a relationship formalized by contractual agreement between a public agency and a private-sector entity that reasonably defines the terms of collaboration in the delivery and financing of a public project.

Real property means any land, whether raw or improved, and includes structures, fixtures, appurtenances, and other permanent improvements, excluding moveable machinery and equipment.

Recipient means an entity receiving EDA investment assistance, including any successor to the entity approved by EDA in writing. If investment assistance is awarded to more than one recipient under a single award, the recipients are referred to as "co-recipients" and, unless otherwise provided in the terms and conditions of the investment assistance, each co-recipient is jointly and severally liable for fulfilling the terms of the investment assistance.

Region or *Regional* means an economic unit of human, natural, technological, capital, or other resources, defined geographically. Geographic areas comprising a region need not be contiguous or defined by political boundaries, but should constitute a cohesive area capable of undertaking self-sustained economic development.

Regional innovation clusters or *RICs* means a geographically bounded network of similar, synergistic, or complementary entities that are engaged in or with a particular industry sector and its related sectors; have active channels for business transactions and communication; share specialized infrastructure, labor markets, and services; and leverage the region's unique competitive strengths to stimulate innovation and create jobs.

Regional Innovation Program means the program enacted by Stevenson-Wydler at 15 U.S.C. 3722.

Regional Innovation Research and Information Program or *RIRI Program* means the program authorized by 15 U.S.C. 3722(c).

Regional Innovation Strategies Program or *RIS Program* means the cluster grant program authorized by 15 U.S.C. 3722(b).

Science or research park means a property-based venture that has: Master-planned property and buildings designed primarily for private-public research and development activities, high technology and science-based companies, and research and development support services; a contractual or operational relationship with one or more science- or research-related institutions of higher education or governmental or nonprofit research laboratories; a primary mission to promote research and development through industry partnerships, assisting in the growth of new ventures and promoting innovation-driven economic development; a role in facilitating the transfer of technology and business skills between researchers and industry teams; and a role in promoting technology-led economic development for the community or region in which the park is located.

Secretary means the Secretary of Commerce.

State means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, or any other territory or possession of the United States.

United States means all of the States.

Subpart B—Regional Innovation Strategies Program

§ 312.4 Purpose and scope of the Regional Innovation Strategies Program.

Under the RIS Program, EDA makes grants on a competitive basis to eligible applicants to foster connected, innovation-centric economic regions that support commercialization and entrepreneurship. The grants are intended to build public and private capacity to invent and improve products and services and to bring those products and services to market through a process often referred to as technology commercialization, as demonstrated by methodologically sound metrics for output and outcome.

§ 312.5 Regional Innovation Strategies Program definitions.

In addition to the defined terms set forth in subpart A, the following term applies specifically to the RIS Program:

Institution of higher education means:

(1) An educational institution in any State that—

(i) Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the requirements of 20 U.S.C. 1091(d);

(ii) Is legally authorized within such State to provide a program of education beyond secondary education;

(iii) Provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the Secretary of Education; and

(iv) Is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted preaccreditation status by such an agency or association that has been recognized by the Secretary of Education for the granting of preaccreditation status, and the Secretary of Education has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

(2) *Additional institutions included.* For purposes of this subpart, the term *Institution of higher education* also includes—

(i) Any school that provides not less than a 1-year program of training to prepare students for gainful employment in a recognized occupation and that meets the provisions of paragraphs (1)(i), (ii), and (iv) of this definition; and

(ii) An educational institution in any State that, in lieu of the requirement in paragraph (1)(i) of this definition, admits as regular students individuals—

(A) Who are beyond the age of compulsory school attendance in the State in which the institution is located; or

(B) Who will be dually or concurrently enrolled in the institution and a secondary school.

§ 312.6 Eligible recipients.

A recipient eligible for investment assistance includes:

(a) A State;

(b) An Indian tribe;

(c) A city or other political subdivision of a State;

(d) An entity that is a nonprofit organization and whose application for funding under the RIS Program is supported by a State or a political subdivision of a State;

(e) An entity that is an institution of higher education, a public-private partnership, a science or research park, a Federal laboratory, or an economic development organization or similar entity, and whose application for funding under the RIS Program is supported by a State or a political subdivision of a State; or

(f) A consortium of any of the entities described in paragraphs (a) through (e) of this section.

§ 312.7 Eligible project activities.

(a) Activities eligible for a RIS Program grant include:

(1) Feasibility studies;

(2) Planning activities;

(3) Technical assistance;

(4) Developing or strengthening communication and collaboration between and among participants of a regional innovation cluster;

(5) Attracting additional participants to a regional innovation cluster;

(6) Facilitating market development of products and services of a regional innovation cluster, including through demonstration, deployment, technology transfer, and commercialization activities;

(7) Developing relationships between a regional innovation cluster and entities or clusters in other regions;

(8) Interacting with the public and State and local governments to meet the goals of the regional innovation cluster;

(9) Purchase of equipment, but only to the extent that such equipment is used to support another eligible activity as described in this section (the recipient may be required to secure and record the Federal interest in the equipment);

(10) Modifications or renovations of a facility that are necessary to install equipment; and

(11) Any other activity determined appropriate by the Assistant Secretary.

(b) An ineligible activity includes, but is not limited to:

(1) Use of Federal funds or matching share for equity investments;

(2) Acquisition or improvement of real property;

(3) Construction except to the extent provided in paragraph (a)(10) of this section; and

(4) Lending programs, such as a direct loan program or capitalizing a revolving loan fund.

§ 312.8 Investment rates.

(a) *Minimum investment rate.* There is no minimum investment rate for a project.

(b) *Maximum investment rate.* The maximum investment rate for a project shall not exceed 50 percent.

§ 312.9 Matching share requirements.

The required matching share of a project's eligible costs may consist of cash or in-kind contribution(s) whose value can be readily determined, verified, and justified. Applicants must show at the time of application that the matching share is committed to the project, will be available as needed, and is not or will not be conditioned or encumbered in any way that would preclude its use consistent with the requirements of the investment assistance. EDA shall determine at its sole discretion whether the matching share documentation adequately addresses the requirements of this section.

§ 312.10 Application components.

In addition to the criteria set forth in the FFO, to be considered for a RIS Program grant, eligible applicants must provide the following information:

(a) A description of the regional innovation cluster supported by the proposed activity;

(b) The extent to which the regional innovation cluster is supported by the private sector, State and local units of government, and other relevant stakeholders;

(c) The methods that participants in the regional innovation cluster will use to encourage and solicit participation by all types of entities that might benefit from participation, including newly formed entities and rival existing participants;

(d) The extent to which the regional innovation cluster is likely to stimulate innovation and have a positive effect on regional economic growth and development;

(e) The capacity of participants in the regional innovation cluster to access, or contribute to, a well-trained workforce;

(f) The ability of participants in the regional innovation cluster to attract additional funds to support the cluster with non-Federal funds; and

(g) The likelihood that participants in the regional innovation cluster will be able to sustain activities after the grant expires.

§ 312.11 Application evaluation and selection criteria.

(a) EDA will evaluate and select complete applications in accordance with the evaluation criteria, funding priority considerations, availability of funding, competitiveness of the application, and requirements set forth in section 27(b) of Stevenson-Wydler, the FFO, and other applicable Federal statutes and regulations. All awards are subject to the availability of funds.

(b) EDA will endeavor to notify applicants as soon as practicable regarding whether their applications are selected for funding.

(c) Stevenson-Wydler does not require nor does EDA provide an appeal process for denial of applications for EDA investment assistance.

§ 312.12 General terms and conditions for investment assistance.

RIS Program grants are subject to all requirements contained in part 302 of this chapter, except §§ 302.2, 302.3, 302.9, and 302.10.

Subpart C—Regional Innovation Research and Information Program

§§ 312.13 through 312.17 [Reserved]

Dated: September 6, 2016.

Roy K.J. Williams,

Assistant Secretary for Economic Development.

[FR Doc. 2016–22286 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–24–P

SUSQUEHANNA RIVER BASIN COMMISSION

18 CFR Parts 806 and 808

Review and Approval of Projects

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice of proposed rulemaking; notice of public hearings.

SUMMARY: This document contains proposed rules that would amend the regulations of the Susquehanna River Basin Commission (Commission) to clarify application requirements and standards for review of projects, amend the rules dealing with the mitigation of consumptive uses, add a subpart to provide for registration of grandfathered projects, and revise requirements dealing with hearings and enforcement actions. These rules are designed to enhance the Commission's existing authorities to manage the water resources of the basin and add regulatory clarity.

DATES: In addition, the Commission will be holding two informational webinars explaining the proposed rulemaking on October 11, 2016, and October 17, 2016. Instructions for registration for the webinars will be posted on the Commission's Web site. Comments on the proposed rulemaking may be submitted to the Commission on or before January 30, 2017. The Commission has scheduled four public hearings on the proposed rulemaking:

1. November 3, 2016, 2 p.m. to 5 p.m. or at the conclusion of public testimony, whichever is sooner; Harrisburg, PA.
2. November 9, 2016, 7 p.m. to 9 p.m. or at the conclusion of public testimony, whichever is sooner; Binghamton, NY.
3. November 10, 2016, 7 p.m. to 9 p.m. or at the conclusion of public testimony, whichever is sooner; Williamsport, PA.
4. December 8, 2016, 1 p.m. to 3 p.m. or at the conclusion of public testimony, whichever is sooner; Annapolis, MD.

The locations of the public hearings are listed in the **ADDRESSES** section of this document.

ADDRESSES: Comments may be mailed to: Jason E. Oyler, Esq., General Counsel, Susquehanna River Basin Commission, 4423 N. Front Street, Harrisburg, PA 17110–1788, or by email to *regcomments@srbc.net*. The public hearings locations are:

1. Harrisburg—Pennsylvania State Capitol (East Wing, Room 8E–B), Commonwealth Avenue, Harrisburg, PA 17120.
2. Binghamton—DoubleTree by Hilton Hotel Binghamton (South Riverside Room), 225 Water Street, Binghamton, NY 13901.
3. Williamsport—Holiday Inn Williamsport (Gallery Room), 100 Pine Street, Williamsport, PA 17701.
4. Annapolis—Loews Annapolis Hotel (Powerhouse-Point Lookout), 126 West Street, Annapolis, MD 21401.

Those wishing to testify are asked to notify the Commission in advance, if possible, at the regular or electronic addresses given below.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, Esq., General Counsel, telephone: 717–238–0423, ext. 1312; fax: 717–238–2436; email: *joyler@srbc.net*. Also, for further information on the proposed rulemaking, visit the Commission's Web site at *http://www.srbc.net*.

SUPPLEMENTARY INFORMATION: The Commission's regulations have not undergone a thorough review since the last comprehensive rulemaking in 2006. Many of these regulations remain unchanged. However, since initial implementation, the Commission recognizes the need for clarity in some sections and statement of procedure in others. These changes are designed to bring clarity and certainty to the regulated community. This rulemaking reflects the efforts of a comprehensive internal review by the Commission staff and review by the Commission's member jurisdictions. The rulemaking centers on a few key areas of the regulations: Project review, consumptive use mitigation, registration of grandfathered projects, and administrative procedures. The Commission proposed this rulemaking to clarify application requirements and standards for review of projects, amend the rules dealing with the mitigation of consumptive uses, add a subpart to provide for registration of grandfathered projects, and revise requirements dealing with hearings and enforcement actions. Because the concept is a new addition to the regulations, the Commission believes that an explanation for the rationale for the proposed rules relating to the registration of grandfathered projects would be helpful for the public.

Sources and Activities That Predate Regulations

The Commission's regulations provide that certain withdrawals and pre-compact consumptive uses that are in excess of the Commission's regulatory thresholds do not require Commission approval under § 806.4(a) if those sources predated regulations, provided there is no environmental harm. This exemption from review and approval is commonly referred to as "grandfathering." Generally, pre-compact consumptive uses initiated prior to January 23, 1971, groundwater withdrawals initiated prior to July 13, 1978, and surface water withdrawals initiated prior to November 11, 1995, are considered "grandfathered" and do not need to apply for a regulatory approval by the Commission. The Commission's current regulations provide several mechanisms by which a grandfathered project must apply for regulatory approval, including a change in the nature of the use, change of ownership, an increase in the quantity of the withdrawal or use, or adding a new source.

However, in enacting the Compact that created the Commission, Congress and the participating states declared that . . .

> the conservation, utilization, development, management and control of the water resources of the Susquehanna River Basin under comprehensive multiple purpose planning will produce the greatest benefits and produce the most efficient service in the public interest. Compact Preamble Sect 1—emphasis added.

The Commission's "Comprehensive Plan for the Water Resources of the Susquehanna Basin" contains an objective to wisely manage the water resources of the Basin to assure short-term resource availability and long-term balance between healthy ecosystems and economic viability (SRBC Comprehensive Plan, 2013). The desired result of one of the key water resource needs, identified as Sustainable Water Development, is to regulate and plan for water resources development in a manner that maintains economic viability, protects instream users, and ensures ecological diversity; and meets immediate and future needs of the people of the basin for domestic, municipal, commercial, agricultural and industrial water supply and recreational activities.

As part of this objective, the Commission recently completed a major effort to characterize water use and availability for the Susquehanna River Basin. The Cumulative Water Use and Availability Study (CWUAS) represents the most comprehensive analysis to date regarding water availability. The Commission is increasingly concerned about the availability of water to meet immediate and future needs as water is needed to satisfy the continuing prospect of growing population and increasing demands for drinking water, freshwater inflow to the Chesapeake Bay, power generation, industrial activity, commercial uses, recreation and ecological diversity. Water resources are neither limitless nor equally distributed across the basin, and in some areas the demand for and use of water resources may be approaching or exceeding the sustainable limit.

As part of the CWUAS, the Commission developed a comprehensive water use database by integrating water use records from the Commission, and its member jurisdictions of New York, Pennsylvania, and Maryland in an unprecedented compilation effort. Compiling accurate water use data is a common challenge for water resource agencies, even recognizing advances in accessing data records through electronic reporting for both the Commission and our member states. The study shows water availability in nearly 1 in 10 watersheds is sufficiently compromised to warrant additional analysis and improved knowledge of patterns of withdrawal and use.

The CWUAS also reveals the limitations of the currently available water use data. While these data include records of regulated public water supply withdrawals for all states, withdrawals for the remaining variety of self-supplied uses are commonly lacking with the exception of those projects regulated by the Commission. Coverage for unregulated withdrawals, including grandfathered projects, is provided through state registration programs and varies widely in data quality and completeness among the member jurisdictions. For the most part, data for consumptive use not regulated by the Commission are absent altogether.

At the time of its formation and adoption of its initial regulations, neither the Commission nor its member jurisdictions conducted any inventory of existing water users, their sources or the quantity of existing water use. Grandfathered water withdrawals and use are clearly factors in the determination of sustainable water availability. The Commission's analysis estimates a total of 760 grandfathered projects with an estimated water use of 970 million gallons per day, which is approximately equal to the total existing regulated consumptive use approved by the Commission. With such large water quantities in question, it is obvious that some of the grandfathered projects are among the largest users of basin waters. Therefore, appropriate regulation and comprehensive planning for the use of the water resources are seriously hampered without accurate and reliable data regarding the quantity of the grandfathered uses and withdrawals. This is even more critical for areas identified as potentially stressed, water challenged or otherwise having limited water availability.

While our member jurisdictions have made efforts to collect water withdrawal data, and the Commission uses that data as available, our member jurisdictions do not comprehensively register consumptive water use. In addition, they do not have comprehensive historic data for legacy water users to effectively determine the quantity of water withdrawn prior to 1995 or the water consumptively used prior to 1971. This lack of comprehensive and reliable data hampers the Commission by creating significant gaps in our knowledge and data of water withdrawals and water use in the basin, which in turn hinders our ability to comprehensively manage the water resources of the basin and fulfill our regulatory and planning functions.

It is, therefore, appropriate for the Commission to act to address this knowledge gap as no other jurisdiction is solely capable of insuring the effectuation of the comprehensive plan. In these regulations the Commission is proposing a mechanism for acquiring accurate water use and withdrawal information for grandfathered projects through a required registration program. It is imperative that we have no misrepresentations about the sustainability of our water supply so that sound water resource decisions can be made for the benefit of all the basin's users. Grandfathered uses and withdrawals represent a longstanding gap in knowledge and, as such, have increasingly become a water management issue in the Commission's regulation and planning for water resources development.

Registration of grandfathered uses and withdrawals will definitively answer questions about the number of grandfathered projects, the locations of their sources, how much water they are withdrawing and from which water bodies and aquifers, and how much of that water they are using consumptively. In short, it will allow water resource decisions to be made with more certainty and confidence. The registration requirements proposed do not require review and approval of dockets under § 806.4 and do not add any new pathways for a grandfathered project to be subject to review and approval if it registers in accordance with the proposed regulation.

The Commission expects the registration of grandfathered uses will achieve a number of crucial goals to allow better management of basin resources. The Commission will receive more consistent and complete data than what can be obtained through voluntary registration programs, such as peak quantities, patterns of usage and accurate locational data for withdrawals and uses. The data required for registration is more easily attainable data from the most recent five years, as opposed to historical data. This data will be more recent and based on more accurate and reliable metering and measurement devices. Registration will eliminate legacy issues by closing the knowledge gap about grandfathered withdrawals from and usage of the water resources of the basin. The information obtained through the registration will allow the Commission staff to conduct thorough water availability analyses.

Registration will also provide more direct benefits to the grandfathered projects by providing the Commission with complete, contemporary withdrawal and usage data that can be utilized by the Commission in evaluating new withdrawals or consumptive uses in the watersheds where the grandfathered projects operate and allow the Commission to better prevent impacts and interference to the operations of grandfathered projects by newer projects. Registration will also provide unambiguous determinations concerning pre-regulation quantities of withdrawals and consumptive uses in the basin for both project sponsors and the Commission, providing much more certainty with regards to how a grandfathered project may operate and retain their existing exempt status and avoid the full project review and approval process. As such, project sponsors can plan and anticipate when they might fall under the Commission's jurisdiction and avoid situations where they unknowingly could fall into noncompliance, as currently happens.

Registration also should provide for ongoing information concerning contemporary water withdrawals and uses at grandfathered projects, to meet Commission management goals of the Comprehensive Plan, including:

- Supporting water conservation measures through monitoring and reporting data;
- Making informed regulatory decisions about cumulative effect on other uses/withdrawals, including analyses for low flow protection (passby flows) and consumptive use mitigation;
- Projecting future water availability to support and inform development decisions, including siting of new facilities critical for water supply, energy development and industrial needs; and
- Identifying critical water planning areas where potential shortages due to drought are projected or intense competition among water users exists.

Registration of grandfathered projects allows the Commission to continue to allow those projects to receive the exemption from the Commission's review and approval under § 806.4 but also fulfills the Commission's need to have accurate, current and reliable data on the amount of the water withdrawals and consumptive use of grandfathered projects to use in the Commission's management decisions for the water resources of the basin. Registration is a one-time event that allows a grandfathered project to continue to operate under the exemption from the Commission's regulations for review and approval of projects, and the only ongoing obligation of project registration is to periodically report withdrawal and usage data. Registration is not review and approval of the project and the proposed rulemaking does not eliminate the grandfathering exemption for projects that register. This means a grandfathered project will not need to meet the requirements and standards set forth in part 806, subparts A through D, which include making an application to Commission, conducting an aquifer test for groundwater withdrawals, evaluation for the sustainability of water withdrawals, evaluation of impact on surface water features, wetlands, other water supplies and wells, establishment of passby flows to protect surface waters, imposition of mitigation for withdrawals or consumptive use, or imposition of conditions or limits on the grandfathered withdrawal or consumptive use. In addition, the Commission has designed the registration to be as simple and accessible as possible to greatly minimize costs, and/or eliminate the need for a grandfathered project to engage a consultant to complete the registration process.

New Subpart E and Revisions to 18 CFR 806.4—Registration of Grandfathered Projects

New subpart E sets forth the rules related to registration of grandfathered projects.

Section 806.40 defines the grandfathered projects within the scope of the regulations and registration requirement.

Section 806.41 provides that grandfathered projects must register within a two-year window or they become subject to review and approval by the Commission in accordance with the Commission's project review regulations and standards. The proposal also contains corresponding changes in § 806.4(a)(1)(iii) and (a)(2)(iv) to clearly provide when a project with some grandfathered aspect or element is subject to review and approval.

The proposed regulations in §§ 806.40(b) and 806.41(c) do not protect grandfathered projects that can be shown to have clearly lost grandfathered status under the regulations in effect at the time the relevant action took place. For example, a grandfathered project that underwent a change of ownership, but did not seek review and approval as required by the §§ 806.4 and 806.6, is not eligible to register and will be required to submit an application for review and approval of the project.

Other projects that have a grandfathered aspect, but that do not withdraw or use water at a jurisdictional threshold to qualify as a grandfathered project under § 806.40, are not eligible to register and will be subject to review and approval if those projects ever withdraw or consumptively use water above the jurisdictional thresholds, pursuant to §§ 806.4(a)(1)(iii)(B), 806.4(a)(2)(iv)(B), and 806.40(c).

Paragraph 806.41(e) provides that the Commission may establish fees in accordance with § 806.35. The Commission will establish any registration fee simultaneously at the time of the adoption of a final rule. Because the amount of any fee will likely be of interest to the public, the Commission, in conjunction with this proposed rulemaking, is proposing a staggered fee for registration. Section 806.41(a) establishes a two-year window during which grandfathered projects must register. The Commission proposes that project sponsors that submit their registration within the first 6 months of that two-year registration period will pay no fee. During the next 6 months of the registration period, the fee will be $500. During the last year of the registration period, the fee will be

$1,000. The registration fee is a one-time fee. By providing a no fee option during the first six months of the registration period, the Commission intends to provide relief for project sponsors that may be concerned about payment of a registration fee and to incentivize project sponsors to register sooner which will lead to an earlier submission of the data that the Commission is seeking through the registration process.

Section 806.42 outlines the primary information needs of the Commission for registration of withdrawals and consumptive uses. Because of the problems frequently encountered with producing reliable historical data, paragraph 806.42(a)(6) requests the most recent five years of quantity data for a project's withdrawals and consumptive use for at least the past five calendar years.

Section 806.43 provides that the Commission shall review the project's current metering and monitoring for its grandfathered withdrawals and consumptive uses. The Commission may require the project to follow a metering and monitoring plan to ensure that withdrawal and use quantities are accurate and reliable. This section also provides for ongoing reporting of quantities for grandfathered withdrawals and consumptive uses. The Commission may accept quantities reported under the requirements of the applicable member jurisdiction in lieu of additional monitoring data. This information is vital to the Commission in its ongoing evaluation of the water resources of the basin and will be used in revising the Commission's Comprehensive Plan, in its ongoing evaluation of cumulative water use in the basin and to provide data to assess and evaluate impacts of new projects seeking review and approval by the Commission.

Sections 806.44 and 806.45 provide a process for the determination of grandfathered quantities for withdrawals and consumptive uses. This determination will be made by the Executive Director taking into account the most reliable data. An increase above this amount would require review and approval under §§ 806.4(a)(1)(iii)(A) and 806.4(a)(2)(iv)(A). A project will be able to appeal this determination to the Commission. Any hearing conducted will be done in accordance with the Commission's appeal procedures in Part 808.

Project Review Application Procedures—18 CFR Subpart B

Section 806.11 is revised to include a specific reference to § 801.12(c)(2), noting that preliminary consultations, or pre-application meetings, are encouraged but not mandatory except for electric power generation projects.

Section 806.12 is revised to clarify when project sponsors will perform a constant-rate aquifer test and to clarify that reviews of aquifer test plan submittals are subject to termination of review under § 806.16.

Section 806.14 detailing the contents of applications to the Commission is rewritten. The new section as proposed better aligns to the actual items sought in the Commission's applications, as well as provides required items specific to each type of approval (*i.e.*, groundwater withdrawal, surface water withdrawal, consumptive use). The proposed regulation includes new requirements specific to projects such as mine and construction dewatering, water resources remediation, and gravity-drained acid mine drainage (AMD) remediation facilities to align with the newly proposed standards for these types of projects under § 806.23(b)(5). The proposal also includes specific requirements for renewal applications.

This section as rewritten retains the requirement for an alternatives analysis for new projects, if prompted by a request from the Commission. However, for new surface water withdrawal projects, an alternatives analysis *must* be performed in settings with a drainage area of 50 miles square or less, or in a waterway with exceptional water quality.

Section 806.15 regarding notice requirements for applications is revised to provide notice to appropriate county agencies, removing the specific reference to county planning agencies. Appropriate county agencies include the county governing body, county planning agencies and county conservation districts. Section 806.15(b)(3) is added to allow the Commission or Executive Director to allow notification of property owners by other means where the property is served by a public water supply.

Standards for Review and Approval—18 CFR Subpart C

Section 806.21 is revised to mention that a project must be "feasible" to align it with the standard presently used for projects during review to determine that they are feasible from both a financial and engineering perspective.

Section 806.22 regarding standards for the consumptive use of water is revised. The proposed revisions lower the 90-day standard for consumptive use mitigation to 45 days and require a mitigation plan that can have several elements and encourages blended mitigation options. The purpose of these changes is to reduce the barriers to project sponsors finding their own mitigation and to correspondingly reduce the number of projects paying the consumptive use mitigation fee. Analysis of the past 100 plus years of river flow records show that the overwhelming majority of low flow/drought events in the Basin are adequately covered by a 45-day consumptive use mitigation standard.

Section 806.22(b) is also revised to clarify that when a project is subject to review and approval and also has an element of pre-compact consumptive use, the project sponsor will be required to provide mitigation going forward for this consumptive use if the project is located in a water critical area. The location of a project in a water critical area will also be a factor used by the Commission in determining the manner of acceptable mitigation under paragraph (c). A definition of water critical area is included in § 806.3 that will rely on both the existing member jurisdiction designations and the ongoing efforts by the Commission to identify areas where water resources are limited or the demand for water has exceeded or is close to exceeding the sustainable supply. Any action to identify a water critical area will be taken by a separate action of the Commission and may be subject to a public hearing under the revisions to § 808.1(b)(4).

Paragraph 806.22(e)(1) is amended to allow a project sourced by more than one public water supply to be eligible for an Approval by Rule for consumptive use as long as the public water supplies are the sole source of water for the project. New § 806.22(e)(2) and (3) were added so both the Approvals by Rule in paragraph (e) and (f) had matching procedures. The time frame for making notice was extended to 20 days in § 806.22(f)(3) to match the changes previously made to § 806.15, related to notice, during the last Commission rulemaking.

Section 806.23 related to standards for withdrawals is amended to include elements that presently form the basis of conditions to approvals for withdrawals. The proposal clarifies that the Commission can establish conditions based on the project's effect on groundwater and surface water availability, including cumulative uses and effects on wetlands. This section is clarified to expressly include the Commission's practice of establishing and requiring a total system limit on projects.

A new § 806.23(b)(5) is added to provide special review provisions for projects consisting of mine dewatering, water resources remediation, and gravity-drained AMD facilities. Because the nature of these types of facilities is fundamentally different from the other withdrawal projects that come before the Commission and because they are heavily regulated by our member jurisdictions, the Commission may appropriately limit consideration of adverse impacts of these projects on groundwater availability, causing permanent loss of aquifer storage and lowering of groundwater levels.

Hearings and Enforcement Actions—Part 808

Section 808.1 is revised. The revised section in paragraph (a) identifies those actions that must have a public hearing pursuant to the Susquehanna River Basin Compact. Paragraph (b) outlines all other instances when the Commission may hold a hearing. No changes are contemplated to how the Commission currently conducts its hearings. Paragraphs (c) through (h) are revised to both update the regulations and also to reflect the Commission's current public hearing procedures.

Section 808.2 is revised to amend the scope and procedure for administrative appeals to the Commission. The non-mandatory appeal language is removed and paragraph (a) is revised to provide a mandatory appeal to the Commission of a final action or decision made by the Executive Director, including a non-exclusive list of appealable actions. Where the Commission itself takes a final action, including actions or decisions it makes on appeal of Executive Director actions, those decisions c must be appealed to the appropriate federal district court in accordance with the provisions of section 3.10 of the Compact. This section also clarifies that the Commission will determine the manner in which it will hear an appeal, including whether a hearing is granted or whether the issue will be decided through submission of briefs.

Section 808.11 is revised to expressly recognize directives issued from Commission staff.

Section 808.14 is revised to provide the Executive Director broader authority to issue compliance orders. These orders would be appealable to the Commission. Paragraph (e) is added to expressly recognize Consent Orders and Agreements in the regulations. These agreements are vital to the Commission in fulfilling its compliance and enforcement obligations under the Compact and allow for a constructive resolution of most enforcement actions.

Section 808.15 is revised to allow the Executive Director to determine the appropriateness of a civil penalty in the first instance in a show cause proceeding. Any decision of the Executive Director is appealable to the Commission. Paragraph (c) is added to reflect the Commission's intent that any finding regarding the imposition of a civil penalty by the Executive Director shall be based on the relevant policies and guidelines adopted by the Commission, as well as the relevant law and facts and information presented as a part of the show cause proceeding.

Section 808.16 regarding civil penalty criteria is revised to be consistent with other changes in this proposed rulemaking, as well as add a new factor regarding the punitive effect of a civil penalty on a violator.

Section 808.17 is revised to be consistent with other changes in the proposed rulemaking.

Section 808.18 is revised to allow the Executive Director to enter into settlement agreements to resolve enforcement actions. Currently all settlement agreements must be brought to the Commission for approval at the Commission's quarterly meeting with the exception of settlements under $10,000 pursuant to Commission Resolution 2014–15. The revision provides greater authority for the Executive Director to approve settlement agreements, but retains the ability of the Commission to require certain types of settlements to be submitted for the Commission's approval through adoption of a Resolution.

Miscellaneous Changes

Section 806.1 is revised to include diversions within the scope of Part 806, which was an omission. The address of the Commission is also updated.

Section 806.3 related to definitions is revised. The definition of facility is revised to include consumptive use, which was an omission. The definition of production fluids is revised to include other fluids associated with the development of natural gas resources. The Commission routinely receives questions regarding other fluids, such as stormwater captured and stored in a drilling rig apparatus, and what rules apply to such water. The Commission is electing to treat all such water as a production fluid to ensure it is accounted for. A definition of wetland is added that mirrors the definition used by the U.S. Army Corps of Engineers for its regulatory program.

Section 806.4 related to projects requiring review and approval is revised, in addition to the changes discussed regarding new subpart E. Paragraph (a) is revised to clarify that aquifer testing pursuant to § 806.12 is not a project governed by § 806.4. Paragraph (a)(2), related to the regulation of withdrawals, is revised to clarify that a project includes all of its sources and to include a reference to the general project review standards in § 806.21.

A new paragraph (a)(3)(vii) is added to allow flowback and production fluids into the basin for in-basin treatment or disposal. The Commission does not want its regulations to be a disincentive to treatment of flowback where the activity is conducted in accordance with the environmental standards and requirements of its member jurisdictions.

Section 806.30 related to monitoring is revised and clarified. The revisions provide that measuring, metering or monitoring devices must be installed per the specifications and recommendations of the device's manufacturer. The revisions clarify that the Commission may require measurement of groundwater levels in wells other than production wells and may require other monitoring for environmental impacts.

Section 806.31 related to the term of approvals is revised to provide that if a project sponsor submits an application one month prior to the expiration of an ABR or NOI approval, the project sponsor may continue to operate under the expired approval while the Commission reviews the application. In the Commission's experience, the six month time frame currently in the regulation and still applicable to existing Commission docket approvals is longer than necessary for ABR approvals.

Transition Issues

The Commission is contemplating that all changes proposed in this rulemaking will take effect immediately upon publication in the **Federal Register**, with the exception of the adoption of Subpart E (related to registration of grandfathered projects) and the corresponding changes to § 806.4(a)(1)(iii) and (a)(2)(iv), which would be effective six months after the date of publication in the **Federal Register**.

List of Subjects in 18 CFR Parts 806 and 808

Administrative practice and procedure, Water resources.

Accordingly, for the reasons set forth in the preamble, the Susquehanna River Basin Commission proposes to amend 18 CFR parts 806 and 808 as follows:

PART 806—REVIEW AND APPROVAL OF PROJECTS

■ 1. The authority citation for part 806 continues to read as follows:

Authority: Secs. 3.4, 3.5(5), 3.8, 3.10 and 15.2, Public Law 91–575, 84 Stat. 1509 *et seq.*

■ 2. Amend § 806.1 by revising paragraphs (a) and (f) to read as follows:

§ 806.1 Scope.

(a) This part establishes the scope and procedures for review and approval of projects under section 3.10 of the Susquehanna River Basin Compact, Public Law 91–575, 84 Stat. 1509 *et seq.*, (the compact) and establishes special standards under section 3.4(2) of the compact governing water withdrawals, the consumptive use of water, and diversions. The special standards established pursuant to section 3.4(2) shall be applicable to all water withdrawals and consumptive uses in accordance with the terms of those standards, irrespective of whether such withdrawals and uses are also subject to project review under section 3.10. This part, and every other part of 18 CFR chapter VIII, shall also be incorporated into and made a part of the comprehensive plan.

* * * * *

(f) Any Commission forms or documents referenced in this part may be obtained from the Commission at 4423 North Front Street, Harrisburg, PA 17110, or from the Commission's Web site at *http://www.srbc.net.*

■ 3. In § 806.3:

■ a. Revise the definitions for "Facility" and "Production fluids"; and

■ b. Add, in alphabetical order, definitions for "Water critical area" and "Wetland".

The revisions and additions read as follows:

§ 806.3 Definitions.

* * * * *

Facility. Any real or personal property, within or without the basin, and improvements thereof or thereon, and any and all rights of way, water, water rights, plants, structures, machinery, and equipment acquired, constructed, operated, or maintained for the beneficial use of water resources or related land uses or otherwise including, without limiting the generality of the foregoing, any and all things and appurtenances necessary, useful, or convenient for the control, collection, storage, withdrawal, diversion, consumptive use, release, treatment, transmission, sale, or exchange of water; or for navigation thereon, or the development and use of hydroelectric energy and power, and public recreational facilities; of the propagation of fish and wildlife; or to conserve and protect the water resources of the basin or any existing or future water supply source, or to facilitate any other uses of any of them.

* * * * *

Production fluids. Water or formation fluids recovered at the wellhead of a producing hydrocarbon well as a byproduct of the production activity or other fluids associated with the development of natural gas resources.

* * * * *

Water critical area. A watershed or sub-watershed identified by the Commission where there are significantly limited water resources, where existing or future demand for water exceeds or has the potential to exceed the safe yield of available surface water and/or groundwater resources, or where the area has been identified or designated by a member jurisdiction as requiring more intensive water planning.

* * * * *

Wetlands. Those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas.

* * * * *

■ 4. Amend § 806.4 by revising paragraphs (a) introductory text, paragraph (a)(1)(iii), (a)(2) introductory text, and paragraph (a)(2)(iv), and adding paragraph (a)(3)(vii) to read as follows:

§ 806.4 Projects requiring review and approval.

(a) Except for activities relating to site evaluation, to aquifer testing under § 806.12 or to those activities authorized under § 806.34, no person shall undertake any of the following projects without prior review and approval by the Commission. The project sponsor shall submit an application in accordance with subpart B of this part and shall be subject to the applicable standards in subpart C of this part.

(1) * * *

(iii) With respect to projects that existed prior to January 23, 1971, any project:

(A) Registered in accordance with subpart E of this part that increases its consumptive use by any amount over the quantity determined under § 806.44;

(B) Increasing its consumptive use to an average of 20,000 gpd or more in any consecutive 30-day period; or

(C) That fails to register its consumptive use in accordance with subpart E of this part.

* * * * *

(2) *Withdrawals.* Any project, including all of its sources, described below shall require an application to be submitted in accordance with § 806.13, and shall be subject to the standards set forth in §§ 806.21 and 806.23. Hydroelectric projects, except to the extent that such projects involve a withdrawal, shall be exempt from the requirements of this section regarding withdrawals; provided, however, that nothing in this paragraph shall be construed as exempting hydroelectric projects from review and approval under any other category of project requiring review and approval as set forth in this section, § 806.5, or part 801 of this chapter. The taking or removal of water by a public water supplier indirectly through another public water supply system or another water user's facilities shall constitute a withdrawal hereunder.

* * * * *

(iv) With respect to groundwater projects that existed prior to July 13, 1978, surface water projects that existed prior to November 11, 1995, or projects that existed prior to January 1, 2007, with multiple sources involving a withdrawal of a consecutive 30-day average of 100,000 gpd or more that did not require Commission review and approval, any project:

(A) Registered in accordance with Subpart E that increases its withdrawal by any amount over the quantity determined under § 806.44;

(B) Increasing its withdrawal individually or cumulatively from all sources to an average of 100,000 gpd or more in any consecutive 30-day period; or

(C) That fails to register its withdrawals in accordance with subpart E.

* * * * *

(3) * * *

(vii) The diversion of any flowback or production fluids from hydrocarbon development projects located outside the basin to an in-basin treatment or disposal facility authorized under separate government approval to accept flowback or production fluids, shall not be subject to separate review and approval as a diversion under this paragraph, provided the fluids are handled, transported and stored in compliance with all standards and requirements of the applicable member jurisdiction.

* * * * *

■ 5. Amend § 806.11 by revising paragraph (b) to read as follows:

§ 806.11 Preliminary consultations.

* * * * *

(b) Except for project sponsors of electric power generation projects under § 801.12(c)(2) of this chapter, preliminary consultation is optional for the project sponsor (except with respect to aquifer test plans under § 806.12) but shall not relieve the sponsor from complying with the requirements of the compact or with this part.

■ 6. Amend § 806.12 by revising paragraph (a) and adding paragraph (f) to read as follows:

§ 806.12 Constant-rate aquifer testing.

(a) Prior to submission of an application pursuant to § 806.13, a project sponsor seeking approval for a new groundwater withdrawal, a renewal of an expiring groundwater withdrawal, or an increase of a groundwater withdrawal shall perform a constant-rate aquifer test in accordance with this section.

* * * * *

(f) Review of submittals under § 806.12 may be terminated by the Commission in accordance with the procedures set forth in § 806.16.

■ 7. Revise § 806.14 to read as follows:

§ 806.14 Contents of application.

(a) Applications for a new project or a major modification to an existing approved project shall include, but not be limited to, the following information and, where applicable, shall be subject to the requirements in paragraph (b) of this section and submitted on forms and in the manner prescribed by the Commission.

(1) Identification of project sponsor including any and all proprietors, corporate officers or partners, the mailing address of the same, and the name of the individual authorized to act for the sponsor.

(2) Project location, including latitude and longitude coordinates in decimal degrees accurate to within 10 meters, the project location displayed on a map with a 7.5-minute USGS topographic base, and evidence of legal access to the property upon which the project is proposed.

(3) Project description, including: Purpose, proposed quantity to be withdrawn or consumed, if applicable, and identification of all water sources related to the project including location and date of initiation of each source.

(4) Anticipated impact of the project, including impacts on existing water withdrawals, nearby surface waters, and threatened or endangered species and its habitats.

(5) The reasonably foreseeable need for the proposed quantity of water to be withdrawn or consumed, including supporting calculations, and the projected demand for the term of the approval.

(6) A metering plan that adheres to § 806.30.

(7) Evidence of coordination and compliance with member jurisdictions regarding all necessary permits or approvals required for the project from other federal, state or local government agencies having jurisdiction over the project.

(8) Project estimated completion date and estimated construction schedule.

(9) Draft notices required by § 806.15.

(10) The Commission may also require the following information as deemed necessary:

(i) Engineering feasibility;

(ii) Ability of the project sponsor to fund the project.

(b) Additional information is required for a new project or a major modification to an existing approved project as follows.

(1) *Surface water.* (i) Water use and availability.

(ii) Project setting, including surface water characteristics, identification of wetlands, and site development considerations.

(iii) Description and design of intake structure.

(iv) Anticipated impact of the proposed project on local flood risk, recreational uses, fish and wildlife and natural environment features.

(v) Alternatives analysis for a withdrawal proposed in settings with a drainage area of 50 miles square or less, or in a waterway with exceptional water quality, or as required by the Commission.

(2) *Groundwater*—(i) *Constant-rate aquifer tests.* With the exception of mining related withdrawals solely for the purpose of dewatering; construction dewatering withdrawals and withdrawals for the sole purpose of groundwater or below water table remediation generally which are addressed in paragraph (b)(6) of this section, the project sponsor shall provide an interpretative report that includes all monitoring and results of a constant-rate aquifer test consistent with § 806.12 and an updated groundwater availability estimate if changed from the aquifer test plan. The project sponsor shall obtain Commission approval of the test procedures prior to initiation of the constant-rate aquifer test.

(ii) Water use and availability.

(iii) Project setting, including nearby surface water features.

(iv) Groundwater elevation monitoring plan for all production wells.

(v) Alternatives analysis as required by the Commission.

(3) *Consumptive use.* (i) Consumptive use calculations, and a mitigation plan consistent with § 806.22(b).

(ii) Water conservation methods, design or technology proposed or considered

(iii) Alternatives analysis as required by the Commission.

(4) *Into basin diversions.* (i) Provide the necessary information to demonstrate that the proposed project will meet the standards in § 806.24(c).

(ii) Identification of the source and water quality characteristics of the water to be diverted.

(5) *Out of basin diversions.* (i) Provide the necessary information to demonstrate that the proposed project will meet the standards in § 806.24(b).

(ii) Project setting.

(6) Other projects, including without limitation, mine dewatering, construction dewatering, water resources remediation projects, and gravity-drained AMD remediation facilities

(i) In lieu of aquifer testing, report(s) prepared for any other purpose or as required by other governmental regulatory agencies that provides a demonstration of the hydrogeologic and/or hydrologic effects and limits of said effects due to operation of the proposed project and effects on local water availability.

(c) All applications for renewal of expiring approved projects shall include, but not be limited to, the following information, and, where applicable, shall be subject to the requirements in paragraph (d) of this section and submitted on forms and in the manner prescribed by the Commission.

(1) Identification of project sponsor including any and all proprietors, corporate officers or partners, the mailing address of the same, and the name of the individual authorized to act for the sponsor.

(2) Project location, including latitude and longitude coordinates in decimal degrees accurate to within 10 meters, the project location displayed on map with a 7.5-minute USGS topographic base, and evidence of legal access to the property upon which the project is located.

(3) Project description, to include, but not be limited to: Purpose, proposed

quantity to be withdrawn or consumed if applicable, identification of all water sources related to the project including location and date of initiation of each source, and any proposed project modifications.

(4) The reasonably foreseeable need for the requested renewal of the quantity of water to be withdrawn or consumed, including supporting calculations, and the projected demand for the term of the approval.

(5) An as-built and approved metering plan.

(6) Copies of permits from member jurisdictions regarding all necessary permits or approvals obtained for the project from other federal, state or local government agencies having jurisdiction over the project.

(7) Copy of any approved mitigation or monitoring plan and any related as-built for the expiring project.

(8) Demonstration of registration of all withdrawals or consumptive uses in accordance with the applicable state requirements.

(9) Draft notices required by § 806.15.

(d) Additional information is required for the following applications for renewal of expiring approved projects.

(1) *Surface water.* (i) Historic water use quantities and timing of use.

(ii) Changes to stream flow or quality during the term of the expiring approval.

(iii) Changes to the facility design.

(iv) Any proposed changes to the previously authorized purpose.

(2) *Groundwater*—(i) *Constant-rate aquifer tests.* The project sponsor shall provide an interpretative report that includes all monitoring and results of any constant-rate aquifer testing previously completed or submitted to support the original approval. In lieu of a testing report, historic operational data pumping and elevation data may be considered. Those projects that did not have constant-rate aquifer testing completed for the original approval that was consistent with § 806.12 or sufficient historic operational pumping and groundwater elevation data may be required to complete constant-rate aquifer testing consistent with § 806.12, prepare and submit an interpretative report that includes all monitoring and results of any constant-rate aquifer test.

(ii) An interpretative report providing analysis and comparison of current and historic water withdrawal and groundwater elevation data with previously completed hydro report.

(iii) Current groundwater availability analysis assessing the availability of water during a 1-in-10 year recurrence interval under the existing conditions within the recharge area and predicted for term of renewal (*i.e.,* other users, discharges, and land development within the groundwater recharge area).

(iv) Groundwater elevation monitoring plan for all production wells.

(3) *Consumptive use.* (i) Consumptive use calculations, and a copy of the approved plan or method for mitigation consistent with § 806.22.

(ii) Changes to the facility design;

(iii) Any proposed changes to the previously authorized purpose;

(4) *Into basin diversion.* (i) Provide the necessary information to demonstrate that the proposed project will meet the standards in § 806.24(c).

(ii) Identification of the source and water quality characteristics of the water to be diverted.

(5) *Out of basin diversion.* (i) Historic water use quantities and timing of use;

(ii) Changes to stream flow or quality during the term of the expiring approval;

(iii) Changes to the facility design;

(iv) Any proposed changes to the previously authorized purpose;

(6) Other projects, including without limitation, mine dewatering, water resources remediation projects, and gravity-drained AMD facilities

(i) Copy of approved report(s) prepared for any other purpose or as required by other governmental regulatory agencies that provides a demonstration of the hydrogeologic and/or hydrologic effects and limits of said effects due to operation of the project and effects on local water availability.

(ii) Any data or reports that demonstrate effects of the project are consistent with those reports provided in paragraph (d)(6)(i).

(iii) Demonstration of continued need for expiring approved water source and quantity.

(e) A report about the project prepared for any other purpose, or an application for approval prepared for submission to a member jurisdiction, may be accepted by the Commission provided the said report or application addresses all necessary items on the Commission's form or listed in this section, as appropriate.

(f) Applications for minor modifications must be complete and will be on a form and in a manner prescribed by the Commission. Applications for minor modifications must contain the following:

(1) Description of the project;

(2) Description of all sources, consumptive uses and diversions related to the project;

(3) Description of the requested modification;

(4) Statement of the need for the requested modification; and

(5) Demonstration that the anticipated impact of the requested modification will not adversely impact the water resources of the basin;

(g) For any applications, the Executive Director or Commission may require other information not otherwise listed in this section.

■ 8. Amend § 806.15 by revising paragraph (a), adding paragraph (b)(3) and revising paragraph (g) to read as follows:

§ 806.15 Notice of application.

(a) Except with respect to paragraphs (h) and (i) of this section, any project sponsor submitting an application to the Commission shall provide notice thereof to the appropriate agency of the member State, each municipality in which the project is located, and the county and the appropriate county agencies in which the project is located. The project sponsor shall also publish notice of submission of the application at least once in a newspaper of general circulation serving the area in which the project is located. The project sponsor shall also meet any of the notice requirements set forth in paragraphs (b) through (f) of this section, if applicable. All notices required under this section shall be provided or published no later than 20 days after submission of the application to the Commission and shall contain a description of the project, its purpose, the requested quantity of water to be withdrawn, obtained from sources other than withdrawals, or consumptively used, and the address, electronic mail address, and phone number of the project sponsor and the Commission. All such notices shall be in a form and manner as prescribed by the Commission

* * * * *

(b) * * *

(3) For groundwater withdrawal applications, the Commission or Executive Director may allow notification of property owners through alternate methods where the property is served by a public water supply.

* * * * *

(g) The project sponsor shall provide the Commission with a copy of the United States Postal Service return receipt for the notifications to agencies of member States, municipalities and appropriate county agencies required under paragraph (a) of this section. The project sponsor shall also provide certification on a form provided by the Commission that it has published the newspaper notice(s) required by this section and made the landowner notifications as required under paragraph (b) of this section, if applicable. Until these items are provided to the Commission, processing of the application will not proceed. The project sponsor shall maintain all proofs of publication and records of notices sent under this section for the duration of the approval related to such notices.

* * * * *

■ 9. Amend § 806.21 by revising paragraphs (a) and (c)(1) to read as follows:

§ 806.21 General standards.

(a) A project shall be feasible and not be detrimental to the proper conservation, development, management, or control of the water resources of the basin.

* * * * *

(c) * * *

(1) The Commission may suspend the review of any application under this part if the project is subject to the lawful jurisdiction of any member jurisdiction or any political subdivision thereof, and such member jurisdiction or political subdivision has disapproved or denied the project. Where such disapproval or denial is reversed on appeal, the appeal is final, and the project sponsor provides the Commission with a certified copy of the decision, the Commission shall resume its review of the application. Where, however, an application has been suspended hereunder for a period greater than three years, the Commission may terminate its review. Thereupon, the Commission shall notify the project sponsor of such termination and that the application fee paid by the project sponsor is forfeited. The project sponsor may reactivate the terminated application by reapplying to the Commission, providing evidence of its receipt of all necessary governmental approvals and, at the discretion of the Commission, submitting new or updated information.

* * * * *

■ 10. Revise § 806.22 to read as follows:

§ 806.22 Standards for consumptive use of water.

(a) The project sponsors of all consumptive water uses subject to review and approval under § 806.4, § 806.5, or § 806.6 of this part shall comply with this section.

(b) *Mitigation.* All project sponsors whose consumptive use of water is subject to review and approval under § 806.4, § 806.5, § 806.6, or § 806.17 of this part shall mitigate such consumptive use, including any pre-compact consumptive use if located in a water critical area. Except to the extent that the project involves the diversion of the waters out of the basin, public water supplies shall be exempt from the requirements of this section regarding consumptive use; provided, however, that nothing in this section shall be construed to exempt individual consumptive users connected to any such public water supply from the requirements of this section. The Commission shall require mitigation in accordance with an approved mitigation plan. The proposed mitigation plan shall include the method or combination of the following methods of mitigation:

(1) During low flow periods as may be designated by the Commission for consumptive use mitigation.

(i) Reduce withdrawal from the approved source(s), in an amount equal to the project's total consumptive use, and withdraw water from alternative surface water storage or aquifers or other underground storage chambers or facilities approved by the Commission, from which water can be withdrawn for a period of 45 days without impact.

(ii) Release water for flow augmentation, in an amount equal to the project's total consumptive use, from surface water storage or aquifers, or other underground storage chambers or facilities approved by the Commission, from which water can be withdrawn for a period of 45 days without impact.

(iii) Discontinue the project's consumptive use, except that reduction of project sponsor's consumptive use to less than 20,000 gpd during periods of low flow shall not constitute discontinuance.

(2) Use, as a source of consumptive use water, surface storage that is subject to maintenance of a conservation release acceptable to the Commission. In any case of failure to provide the specified conservation release, such project shall provide mitigation in accordance with paragraph (b)(3) of this section for the calendar year in which such failure occurs, and the Commission will reevaluate the continued acceptability of the conservation release.

(3) Provide monetary payment to the Commission, for all water consumptively used over the course of a year, in an amount and manner prescribed by the Commission.

(4) Implement other alternatives approved by the Commission.

(c) *Determination of manner of mitigation.* The Commission will, in its sole discretion, determine the acceptable manner of mitigation to be provided by project sponsors whose consumptive use of water is subject to review and approval. Such a determination will be made after considering the project's location, including whether the project is located in a water critical area, source characteristics, anticipated amount of consumptive use, proposed method of mitigation and their effects on the purposes set forth in § 806.2 of this part, and any other pertinent factors. The Commission may modify, as appropriate, the manner of mitigation, including the magnitude and timing of any mitigating releases, required in a project approval.

(d) *Quality of water released for mitigation.* The physical, chemical and biological quality of water released for mitigation shall at all times meet the quality required for the purposes listed in § 806.2, as applicable.

(e) *Approval by rule for consumptive uses.* (1) Except with respect to projects involving hydrocarbon development subject to the provisions of paragraph (f) of this section, any project who is solely supplied water for consumptive use by public water supply may be approved by the Executive Director under this paragraph (e) in accordance with the following, unless the Executive Director determines that the project cannot be adequately regulated under this approval by rule.

(2) *Notification of intent.* Prior to undertaking a project or increasing a previously approved quantity of consumptive use, the project sponsor shall submit a notice of intent (NOI) on forms prescribed by the Commission, and the appropriate application fee, along with any required attachments.

(3) Within 20 days after submittal of an NOI under paragraph (f)(2) of this section, the project sponsor shall satisfy the notice requirements set forth in § 806.15.

(4) *Metering, daily use monitoring, and quarterly reporting.* The project sponsor shall comply with metering, daily use monitoring, and quarterly reporting as specified in § 806.30.

(5) *Standard conditions.* The standard conditions set forth in § 806.21 shall apply to projects approved by rule.

(6) *Mitigation.* The project sponsor shall comply with mitigation in accordance with § 806.22 (b)(2) or (3).

(7) *Compliance with other laws.* The project sponsor shall obtain all necessary permits or approvals required for the project from other federal, state or local government agencies having jurisdiction over the project. The Commission reserves the right to modify, suspend or revoke any approval under this paragraph (e) if the project sponsor fails to obtain or maintain such approvals.

(8) The Executive Director may grant, deny, suspend, revoke, modify or condition an approval to operate under

this approval by rule, or renew an existing approval by rule previously granted hereunder, and will notify the project sponsor of such determination, including the quantity of consumptive use approved.

(9) Approval by rule shall be effective upon written notification from the Executive Director to the project sponsor, shall expire 15 years from the date of such notification, and shall be deemed to rescind any previous consumptive use approvals.

(f) *Approval by rule for consumptive use related to unconventional natural gas and other hydrocarbon development.* (1) Any unconventional natural gas development project, or any hydrocarbon development project subject to review and approval under § 806.4, 806.5, or 806.6, shall be subject to review and approval by the Executive Director under this paragraph (f) regardless of the source or sources of water being used consumptively.

(2) *Notification of intent.* Prior to undertaking a project or increasing a previously approved quantity of consumptive use, the project sponsor shall submit a notice of intent (NOI) on forms prescribed by the Commission, and the appropriate application fee, along with any required attachments.

(3) Within 20 days after submittal of an NOI under paragraph (f)(2) of this section, the project sponsor shall satisfy the notice requirements set forth in § 806.15.

(4) The project sponsor shall comply with metering, daily use monitoring and quarterly reporting as specified in § 806.30, or as otherwise required by the approval by rule. Daily use monitoring shall include amounts delivered or withdrawn per source, per day, and amounts used per gas well, per day, for well drilling, hydrofracture stimulation, hydrostatic testing, and dust control. The foregoing shall apply to all water, including stimulation additives, flowback, drilling fluids, formation fluids and production fluids, utilized by the project. The project sponsor shall also submit a post-hydrofracture report in a form and manner as prescribed by the Commission.

(5) The project sponsor shall comply with the mitigation requirements set forth in § 806.22(b).

(6) Any flowback or production fluids utilized by the project sponsor for hydrofracture stimulation undertaken at the project shall be separately accounted for, but shall not be included in the daily consumptive use amount calculated for the project, or be subject to the mitigation requirements of § 806.22(b).

(7) The project sponsor shall obtain all necessary permits or approvals required for the project from other federal, state, or local government agencies having jurisdiction over the project. The Executive Director reserves the right to modify, suspend or revoke any approval under this paragraph (f) if the project sponsor fails to obtain or maintain such approvals.

(8) The project sponsor shall certify to the Commission that all flowback and production fluids have been re-used or treated and disposed of in accordance with applicable state and federal law.

(9) The Executive Director may grant, deny, suspend, revoke, modify or condition an approval to operate under this approval by rule, or renew an existing approval by rule granted hereunder, and will notify the project sponsor of such determination, including the sources and quantity of consumptive use approved. The issuance of any approval hereunder shall not be construed to waive or exempt the project sponsor from obtaining Commission approval for any water withdrawals or diversions subject to review pursuant to § 806.4(a). Any sources of water approved pursuant to this section shall be further subject to any approval or authorization required by the member jurisdiction.

(10) Approval by rule shall be effective upon written notification from the Executive Director to the project sponsor, shall expire five years from the date of such notification, and supersede any previous consumptive use approvals to the extent applicable to the project.

(11) In addition to water sources approved for use by the project sponsor pursuant to § 806.4 or this section, for unconventional natural gas development or hydrocarbon development, whichever is applicable, a project sponsor issued an approval by rule pursuant to paragraph (f)(9) of this section may utilize any of the following water sources at the drilling pad site, subject to such monitoring and reporting requirements as the Commission may prescribe:

(i) Tophole water encountered during the drilling process, provided it is used only for drilling or hydrofracture stimulation.

(ii) Precipitation or stormwater collected on the drilling pad site, provided it is used only for drilling or hydrofracture stimulation.

(iii) Drilling fluids, formation fluids, flowback or production fluids obtained from a drilling pad site, production well site or hydrocarbon water storage facility, provided it is used only for hydrofracture stimulation, and is handled, transported and stored in compliance with all standards and requirements of the applicable member jurisdiction.

(iv) Water obtained from a hydrocarbon water storage facility associated with an approval issued by the Commission pursuant to § 806.4(a) or by the Executive Director pursuant to this section, provided it is used only for the purposes authorized therein, and in compliance with all standards and requirements of the applicable member jurisdiction.

(12) A project sponsor issued an approval by rule pursuant to paragraph (f)(9) of this section may utilize a source of water approved by the Commission pursuant to § 806.4(a), or by the Executive Director pursuant to paragraph (f)(14) of this section, and issued to persons other than the project sponsor, provided any such source is approved for use in unconventional natural gas development, or hydrocarbon development, whichever is applicable, the project sponsor has an agreement for its use, and at least 10 days prior to use, the project sponsor registers such source with the Commission on a form and in the manner prescribed by the Commission.

(13) A project sponsor issued an approval by rule pursuant to paragraph (f)(9) of this section may also utilize other sources of water, including but not limited to, public water supply or wastewater discharge not otherwise associated with an approval issued by the Commission pursuant to § 806.4(a) or an approval by rule issued pursuant to paragraph (f)(9) of this section, provided such sources are first approved by the Executive Director. Any request for approval shall be submitted on a form and in the manner prescribed by the Commission, shall satisfy the notice requirements set forth in § 806.15, and shall be subject to review pursuant to the standards set forth in subpart C of this part.

(14) A project sponsor issued an approval by rule pursuant to paragraph (f)(9) of this section may utilize water obtained from a hydrocarbon water storage facility that is not otherwise associated with an approval issued by the Commission pursuant to § 806.4(a), or an approval by rule issued pursuant to paragraph (f)(9) of this section, provided such sources are first approved by the Executive Director and are constructed and maintained in compliance with all standards and requirements of the applicable member jurisdiction. The owner or operator of any such facility shall submit a request for approval on a form and in the manner prescribed by the Commission,

shall satisfy the notice requirements set forth in § 806.15, and shall be subject to review pursuant to the standards set forth in subpart C of this part.

(15) The project sponsor shall provide a copy of any registration or source approval issued pursuant to this section to the appropriate agency of the applicable member jurisdiction. The project sponsor shall record on a daily basis, and report quarterly on a form and in a manner prescribed by the Commission, the quantity of water obtained from any source registered or approved hereunder. Any source approval issued hereunder shall also be subject to such monitoring and reporting requirements as may be contained in such approval or otherwise required by this part.

■ 11. Amend § 806.23 by revising paragraphs (b)(2) and (b)(3)(i) and adding paragraph (b)(5) to read as follows:

§ 806.23 Standards for water withdrawals.

* * * * *

(b) * * *

(2) The Commission may deny an application, limit or condition an approval to ensure that the withdrawal will not cause significant adverse impacts to the water resources of the basin. The Commission may consider, without limitation, the following in its consideration of adverse impacts: Lowering of groundwater or stream flow levels; groundwater and surface water availability, including cumulative uses; rendering competing supplies unreliable; affecting other water uses; causing water quality degradation that may be injurious to any existing or potential water use; affecting fish, wildlife or other living resources or their habitat; causing permanent loss of aquifer storage capacity; affecting wetlands; or affecting low flow of perennial or intermittent streams.

(3) * * *

(i) Limit the quantity, timing or rate of withdrawal or level of drawdown, including requiring a total system limit.

* * * * *

(5) For projects consisting of mine dewatering, water resources remediation, and gravity-drained AMD facilities, review of adverse impacts will have limited consideration of groundwater availability, causing permanent loss of aquifer storage and lowering of groundwater levels provided these projects are operated in accordance with the laws and regulations of the member jurisdictions.

■ 12. Amend § 806.30 by revising the introductory text and revising paragraph (a)(4) and adding paragraph (a)(8) to read as follows:

§ 806.30 Monitoring.

The Commission, as part of the project review, shall evaluate the proposed methodology for monitoring consumptive uses, water withdrawals and mitigating flows, including flow metering devices, stream gages, and other facilities used to measure the withdrawals or consumptive use of the project or the rate of stream flow. If the Commission determines that additional flow measuring, metering or monitoring devices are required, these shall be provided at the expense of the project sponsor, installed in accordance with a schedule set by the Commission, and installed per the specifications and recommendations of the manufacturer of the device, and shall be subject to inspection by the Commission at any time.

(a) * * *

(4) Measure groundwater levels in all approved production and other wells, as specified by the Commission.

* * * * *

(8) Perform other monitoring for impacts to water quantity, water quality and aquatic biological communities, as specified by the Commission.

* * * * *

■ 13. Amend § 806.31 by revising paragraphs (d) and (e) to read as follows:

§ 806.31 Term of approvals.

* * * * *

(d) If the Commission determines that a project has been abandoned, by evidence of nonuse for a period of time and under such circumstances that an abandonment may be inferred, the Commission may revoke the approval for such withdrawal, diversion or consumptive use.

(e) If a project sponsor submits an application to the Commission no later than six months prior to the expiration of its existing Commission docket approval or no later than one month prior to the expiration of its existing ABR or NOI approval, the existing approval will be deemed extended until such time as the Commission renders a decision on the application, unless the existing approval or a notification in writing from the Commission provides otherwise.

■ 14. Add subpart E to read as follows:

Subpart E—Registration of Grandfathered Projects

Sec.

806.40 Applicability.
806.41 Registration and eligibility.
806.42 Registration requirements.
806.43 Metering and monitoring requirements.
806.44 Determination of grandfathered quantities.
806.45 Appeal of determination.

§ 806.40 Applicability.

(a) This subpart is applicable to the following projects, which shall be known as grandfathered projects:

(1) The project has an associated average consumptive use of 20,000 gpd or more in any consecutive 30-day period all or part of which is a pre-compact consumptive use that has not been approved by the Commission pursuant to § 806.4.

(2) The project has an associated groundwater withdrawal average of 100,000 gpd or more in any consecutive 30-day period all or part of which was initiated prior to July 13, 1978, that has not been approved by the Commission pursuant to § 806.4.

(3) The project has an associated surface water withdrawal average of 100,000 gpd or more in any consecutive 30-day period all or part of which was initiated prior to November 11, 1995, that has not been approved by the Commission pursuant to § 806.4.

(4) The project (or an element of the project) has been approved by the Commission but has an associated consumptive use or water withdrawal that has not been approved by the Commission pursuant to § 806.4.

(5) Any project not included in paragraphs (a)(2) through (4) of this section that has a total withdrawal average of 100,000 gpd or more in any consecutive 30-day average from any combination of sources which was initiated prior to January 1, 2007, that has not been approved by the Commission pursuant to § 806.4.

(6) Any source associated with a project included in paragraphs (a)(2) through (5) of this section regardless of quantity.

(b) A project, including any source of the project, that can be determined to have been required to seek Commission review and approval under the pertinent regulations in place at the time is not eligible for registration as a grandfathered project.

§ 806.41 Registration and eligibility.

(a) Projects sponsors of grandfathered projects identified in § 806.40 shall submit a registration to the Commission, on a form and in a manner prescribed by the Commission, within two years of the effective date of this regulation.

(b) Any grandfathered project that fails to register under paragraph (a) of this section shall be subject to Commission's review and approval under § 806.4.

(c) Any project that is not eligible to register under paragraph (a) of this section shall be subject to Commission's review and approval under § 806.4.

(d) The Commission may establish fees for obtaining and maintaining registration in accordance with § 806.35.

(e) A registration under this subpart may be transferred pursuant to § 806.6.

§ 806.42 Registration requirements.

(a) Registrations shall include the following information:

(1) Identification of project sponsor including any and all proprietors, corporate officers or partners, the mailing address of the same, and the name of the individual authorized to act for the sponsor.

(2) Description of the project and site in terms of:

(i) Project location, including latitude and longitude coordinates in decimal degrees accurate to within 10 meters.

(ii) Project purpose.

(3) Identification of all sources of water, including the date the source was put into service, each source location (including latitude and longitude coordinates in decimal degrees accurate to within 10 meters), and if applicable, any approved docket numbers.

(4) Identification of current metering and monitoring methods for water withdrawal and consumptive use.

(5) Identification of current groundwater level or elevation monitoring methods at groundwater sources.

(6) All quantity data for water withdrawals and consumptive use for a minimum of the previous five calendar years. If quantity data are not available, any information available upon which a determination of quantity could be made.

(7) For consumptive use, description of processes that use water, identification of water returned to the Basin, history of the use, including process changes, expansions and other actions that would have an impact on the amount of water consumptively used during the past five calendar years.

(8) Based on the data provided, the quantity of withdrawal for each individual source and consumptive use the project sponsor requests to be grandfathered by the Commission.

(9) Any ownership or name changes to the project since January 1, 2007.

(b) The Commission may require any other information it deems necessary for the registration process.

§ 806.43 Metering and monitoring requirements.

(a) As a part of the registration process, the Commission shall review the current metering and monitoring for grandfathered withdrawals and consumptive uses.

(b) The Commission may require a metering and monitoring plan for the project sponsor to follow.

(c) Project sponsors, as an ongoing obligation of their registration, shall report to the Commission all information specified in the grandfathering determination under § 806.44 in a form and manner determined by the Commission. If quantity reporting is required by the member jurisdiction where the project is located, the Commission may accept that reported quantity to satisfy the requirements of this paragraph.

§ 806.44 Determination of grandfathered quantities.

(a) For each registration submitted, the Executive Director shall determine the grandfathered quantity for each withdrawal source and consumptive use.

(b) In making a determination, the following factors should be considered:

(1) The most recent withdrawal and use data;

(2) The reliability and accuracy of the data and/or the meters or measuring devices;

(3) Determination of reasonable and genuine usage of the project, including any anomalies in the usage; and

(4) Other relevant factors.

§ 806.45 Appeal of determination.

(a) A final determination of the grandfathered quantity by the Executive Director must be appealed to the Commission within 30 days from actual notice of the determination.

(b) The Commission shall appoint a hearing officer to preside over appeals under this section. Hearings shall be governed by the procedures set forth in part 808 of this chapter.

PART 808—HEARINGS AND ENFORCEMENT ACTIONS

■ 15. The authority citation for part 808 continues to read as follows:

Authority: Secs. 3.4, 3.5(5), 3.8, 3.10 and 15.2, Pub. L. 91–575, 84 Stat. 1509 *et seq.*

■ 16. Revise § 808.1 to read as follows:

§ 808.1 Public hearings.

(a) A public hearing shall be conducted in the following instances:

(1) Addition of projects or adoption of amendments to the comprehensive plan, except as otherwise provided by section 14.1 of the compact.

(2) Review and approval of diversions.

(3) Imposition or modification of rates and charges.

(4) Determination of protected areas.

(5) Drought emergency declarations.

(6) Hearing requested by a member jurisdiction.

(7) As otherwise required by sections 3.5(4), 4.4, 5.2(e), 6.2(a), 8.4, and 10.4 of the compact.

(b) A public hearing may be conducted by the Commission or the Executive Director in any form or style chosen by the Commission or Executive Director in the following instances:

(1) Proposed rulemaking.

(2) Consideration of projects, except projects approved pursuant to memoranda of understanding with member jurisdictions.

(3) Adoption of policies and technical guidance documents.

(4) Identification of a water critical area.

(5) When it is determined that a hearing is necessary to give adequate consideration to issues related to public health, safety and welfare, or protection of the environment, or to gather additional information for the record or consider new information on a matter before the Commission.

(c) *Notice of public hearing.* At least 20 days before any public hearing required by the compact, notices stating the date, time, place and purpose of the hearing including issues of interest to the Commission shall be published at least once in a newspaper of general circulation in the area affected. In all other cases, at least 20 days prior to the hearing, notice shall be posted on the Commission Web site, sent to the parties who, to the Commission's knowledge, will participate in the hearing, and sent to persons, organizations and news media who have made requests to the Commission for notices of hearings or of a particular hearing. With regard to rulemaking, hearing notices need only be forwarded to the directors of the New York Register, the Pennsylvania Bulletin, the Maryland Register and the **Federal Register**, and it is sufficient that this notice appear in the **Federal Register** at least 20 days prior to the hearing and in each individual state publication at least 10 days prior to any hearing scheduled in that state.

(d) *Standard public hearing procedure.* (1) Hearings shall be open to the public. Participants may be any person, including a project sponsor, wishing to appear at the hearing and make an oral or written statement. Statements shall be made a part of the record of the hearing, and written statements may be received up to and including the last day on which the hearing is held, or within 10 days or a reasonable time thereafter as may be specified by the presiding officer.

(2) Participants are encouraged to file with the Commission at its headquarters

written notice of their intention to appear at the hearing. The notice should be filed at least three days prior to the opening of the hearing.

(e) *Representative capacity.* Participants wishing to be heard at a public hearing may appear in person or be represented by an attorney or other representative. A governmental authority may be represented by one of its officers, employees or by a designee of the governmental authority.

(f) *Description of project.* When notice of a public hearing is issued, there shall be available for inspection, consistent with the Commission's Access to Records Policy, all plans, summaries, maps, statements, orders or other supporting documents which explain, detail, amplify, or otherwise describe the project the Commission is considering. Instructions on where and how the documents may be obtained will be included in the notice.

(g) *Presiding officer.* A public hearing shall be presided over by the Commission chair, the Executive Director, or any member or designee of the Commission or Executive Director. The presiding officer shall have full authority to control the conduct of the hearing and make a record of the same.

(h) *Transcript.* Whenever a project involving a diversion of water is the subject of a public hearing, and at all other times deemed necessary by the Commission or the Executive Director, a written transcript of the hearing shall be made. A certified copy of the transcript and exhibits shall be available for review during business hours at the Commission's headquarters to anyone wishing to examine them. Persons wishing to obtain a copy of the transcript of any hearing shall make arrangements to obtain it directly from the recording stenographer at their expense.

(i) The Commission may conduct any public hearings in concert with any other agency of a member jurisdiction.

■ 17. Revise § 808.2 to read as follows:

§ 808.2 Administrative appeals.

(a) A project sponsor or other person aggrieved by a final action or decision of the Executive Director shall file a written appeal with the Commission within 30 days of the receipt of actual notice by the project sponsor or within 30 days of publication of the action on the Commission's Web site or in the **Federal Register**. Appeals shall be filed on a form and in a manner prescribed by the Commission and the petitioner shall have 20 days from the date of filing to amend the appeal. The following is a non-exclusive list of actions by the Executive Director that are subject to an appeal to the Commission:

(1) A determination that a project requires review and approval under § 806.5 of this chapter;

(2) An approval or denial of an application for transfer under § 806.6 of this chapter;

(3) An approval of a Notice of Intent under a general permit under § 806.17 of this chapter.

(4) An approval of a minor modification under § 806.18 of this chapter; and

(5) A determination regarding an approval by rule under § 806.22(e) or (f) of this chapter;

(6) A determination regarding an emergency certificate under § 806.34 of this chapter;

(7) Enforcement orders issued under § 808.14;

(8) A finding regarding a civil penalty under § 808.15(c);

(9) A determination of grandfathered quantity under § 806.44 of this chapter;

(10) A decision to modify, suspend or revoke a previously granted approval;

(11) A records access determination made pursuant to Commission policy;

(b) The appeal shall identify the specific action or decision being appealed, the date of the action or decision, the interest of the person requesting the hearing in the subject matter of the appeal, and a statement setting forth the basis for objecting to or seeking review of the action or decision.

(c) Any request not filed on or before the applicable deadline established in paragraph (a) of this section hereof will be deemed untimely and such request for a hearing shall be considered denied unless the Commission, upon written request and for good cause shown, grants leave to make such filing nunc pro tunc; the standard applicable to what constitutes good cause shown being the standard applicable in analogous cases under Federal law. Receipt of requests for hearings pursuant to this section, whether timely filed or not, shall be submitted by the Executive Director to the commissioners for their information.

(d) Petitioners shall be limited to a single filing that shall set forth all matters and arguments in support thereof, including any ancillary motions or requests for relief. Issues not raised in this single filing shall be considered waived for purposes of the instant proceeding. Where the petitioner is appealing a final determination on a project application and is not the project sponsor, the petitioner shall serve a copy of the appeal upon the project sponsor within five days of its filing.

(e) The Commission will determine the manner in which it will hear the appeal. If a hearing is granted, the Commission shall serve notice thereof upon the petitioner and project sponsor and shall publish such notice in the **Federal Register**. The hearing shall not be held less than 20 days after publication of such notice. Hearings may be conducted by one or more members of the Commission, or by such other hearing officer as the Commission may designate.

(1) The petitioner may also request a stay of the action or decision giving rise to the appeal pending final disposition of the appeal, which stay may be granted or denied by the Executive Director after consultation with the Commission chair and the member from the affected member State. The decision of the Executive Director on the request for stay shall not be appealable to the Commission under this section and shall remain in full force and effect until the Commission acts on the appeal.

(2) In addition to the contents of the request itself, the Executive Director, in granting or denying the request for stay, will consider the following factors:

(i) Irreparable harm to the petitioner.

(ii) The likelihood that the petitioner will prevail.

(f) The Commission shall grant the hearing request pursuant to this section if it determines that an adequate record with regard to the action or decision is not available, or that the Commission has found that an administrative review is necessary or desirable. If the Commission denies any request for a hearing, the party seeking such hearing shall be limited to such remedies as may be provided by the compact or other applicable law or court rule. If a hearing is granted, the Commission shall refer the matter for hearing to be held in accordance with § 808.3, and appoint a hearing officer.

(g) If a hearing is not granted, the Commission may set a briefing schedule and decide the appeal based on the record before it. The Commission may, in its discretion, schedule and hear oral argument on an appeal.

(h) *Intervention.* (1) A request for intervention may be filed with the Commission by persons other than the petitioner within 20 days of the publication of a notice of the granting of such hearing in the **Federal Register**. The request for intervention shall state the interest of the person filing such notice, and the specific grounds of objection to the action or decision or other grounds for appearance. The hearing officer(s) shall determine whether the person requesting intervention has standing in the matter that would justify their admission as an intervener to the proceedings in accordance with Federal case law.

(2) Interveners shall have the right to be represented by counsel, to present evidence and to examine and cross-examine witnesses.

(i) Where a request for an appeal is made, the 90-day appeal period set forth in section 3.10(6) and Federal reservation (o) of the compact shall not commence until the Commission has either denied the request for or taken final action on an administrative appeal.

■ 18. Revise § 808.11 to read as follows:

§ 808.11 Duty to comply.

It shall be the duty of any person to comply with any provision of the compact, or the Commission's rules, regulations, orders, approvals, docket conditions, staff directives or any other requirement of the Commission.

■ 19. Revise § 808.14 to read as follows:

§ 808.14 Orders.

(a) Whether or not an NOV has been issued, the Executive Director may issue an order directing an alleged violator to cease and desist any action or activity to the extent such action or activity constitutes an alleged violation, or may issue any other order related to the prevention of further violations, or the abatement or remediation of harm caused by the action or activity.

(b) If the project sponsor fails to comply with any term or condition of a docket or other approval, the commissioners or Executive Director may issue an order suspending, modifying or revoking approval of the docket. The commissioners may also, in their discretion, suspend, modify or revoke a docket approval if the project sponsor fails to obtain or maintain other federal, state or local approvals.

(c) The commissioners or Executive Director may issue such other orders as may be necessary to enforce any provision of the compact, the Commission's rules or regulations, orders, approvals, docket conditions, or any other requirements of the Commission.

(d) It shall be the duty of any person to proceed diligently to comply with any order issued pursuant to this section.

(e) The Commission or Executive Director may enter into a Consent Order and Agreement with an alleged violator to resolve non-compliant operations and enforcement proceedings in conjunction with or separately from settlement agreements under § 808.18.

■ 20. Revise § 808.15 to read as follows:

§ 808.15 Show cause proceeding.

(a) The Executive Director may issue an order requiring an alleged violator to show cause why a penalty should not be assessed in accordance with the provisions of this chapter and section 15.17 of the compact. The order to the alleged violator shall:

(1) Specify the nature and duration of violation(s) that is alleged to have occurred.

(2) Set forth the date by which the alleged violator must provide a written response to the order.

(3) Identify the civil penalty recommended by Commission staff.

(b) The written response by the project sponsor should include the following:

(1) A statement whether the project sponsor contests that the violations outlined in the Order occurred;

(2) If the project sponsor contests the violations, then a statement of the relevant facts and/or law providing the basis for the project sponsor's position;

(3) Any mitigating factors or explanation regarding the violations outlined in the Order;

(4) A statement explaining what the appropriate civil penalty, if any, should be utilizing the factors at § 808.16.

(c) Based on the information presented and any relevant policies, guidelines or law, the Executive Director shall make a written finding affirming or modifying the civil penalty recommended by Commission staff.

■ 21. Amend § 808.16 by revising paragraph (a) introductory text and paragraph (a)(7), adding paragraph (a)(8), and revising paragraph (b) to read as follows:

§ 808.16 Civil penalty criteria.

(a) In determining the amount of any civil penalty or any settlement of a violation, the Commission and Executive Director shall consider:

* * * * *

(7) The length of time over which the violation occurred and the amount of water used, diverted or withdrawn during that time period.

(8) The punitive effect of a civil penalty.

(b) The Commission and/or Executive Director retains the right to waive any penalty or reduce the amount of the penalty recommended by the Commission staff under § 808.15(a)(3) should it be determined, after consideration of the factors in paragraph (a) of this section, that extenuating circumstances justify such action.

■ 22. Revise § 808.17 to read as follows:

§ 808.17 Enforcement of penalties, abatement or remedial orders.

Any penalty imposed or abatement or remedial action ordered by the Commission or the Executive Director shall be paid or completed within such time period as shall be specified in the civil penalty assessment or order. The Executive Director and Commission counsel are authorized to take such additional action as may be necessary to assure compliance with this subpart. If a proceeding before a court becomes necessary, the penalty amount determined in accordance with this part shall constitute the penalty amount recommended by the Commission to be fixed by the court pursuant to section 15.17 of the compact.

■ 23. Revise § 808.18 to read as follows:

§ 808.18 Settlement by agreement.

(a) An alleged violator may offer to settle an enforcement action by agreement. The Executive Director may enter into settlement agreements to resolve an enforcement action. The Commission may, by Resolution, require certain types of enforcement actions or settlements to be submitted to the Commission for action or approval.

(b) In the event the violator fails to carry out any of the terms of the settlement agreement, the Commission or Executive Director may reinstitute a civil penalty action and any other applicable enforcement action against the alleged violator.

Dated: September 15, 2016.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2016–22668 Filed 9–20–16; 8:45 am]

BILLING CODE 7040–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[PS Docket No. 16–269, FCC 16–117]

Procedures for Commission Review of State Opt-Out Requests From the FirstNet Radio Access Network

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document the Commission opens a new proceeding relating to the National Public Safety Broadband Network being implemented by the First Responder Network Authority (FirstNet). The proceeding seeks comment on proposed procedures for administering the Commission's role in the State opt-out process from the

FirstNet radio access network as provided under the Middle Class Tax Relief and Job Creation Act of 2012, as well as on the Commission's implementation of the specific statutory standards by which it is obligated to evaluate State opt-out applications.

DATES: Comments are due on or before October 21, 2016 and reply comments are due on or before November 21, 2016.

ADDRESSES: You may submit comments, identified by PS Docket No. 16–269–87, by any of the following methods:

- *Federal Communications Commission's Web site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Roberto Mussenden, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418–1428.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, PS Docket No. 16–269, FCC 16–117, released on August 25, 2016. The document is available for download at *http://fjallfoss.fcc.gov/edocs_public/.* The complete text of this document is also available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

1. In the Notice of Proposed Rulemaking (NPRM), the Commission opens a new proceeding relating to the National Public Safety Broadband Network (NPSBN) being implemented by the First Responder Network Authority (FirstNet) pursuant to the provisions of the Middle Class Tax Relief and Job Creation Act of 2012 ("Public Safety Spectrum Act" or "Act"). The NPRM seeks comment on proposed procedures for administering the Commission's role in the State opt-out process from the FirstNet radio access network as provided under the Act, as well as on the Commission's implementation of the specific statutory standards by which it is obligated to evaluate State opt-out applications.

2. Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments in PS Docket No. 16–269 on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

3. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.

4. *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

5. Commenters who file information that they believe should be withheld from public inspection may request confidential treatment pursuant to § 0.459 of the Commission's rules. Commenters should file both their original comments for which they request confidentiality and redacted comments, along with their request for confidential treatment. Commenters should not file proprietary information electronically. See Examination of Current Policy Concerning the Treatment of Confidential Information Submitted to the Commission, Report and Order, 13 FCC Rcd 24816 (1998), Order on Reconsideration, 14 FCC Rcd 20128 (1999). Even if the Commission grants confidential treatment, information that does not fall within a specific exemption pursuant to the Freedom of Information Act (FOIA) must be publicly disclosed pursuant to an appropriate request. See 47 CFR 0.461; 5 U.S.C. 552. We note that the Commission may grant requests for confidential treatment either conditionally or unconditionally. As such, we note that the Commission has the discretion to release information on public interest grounds that does fall within the scope of a FOIA exemption.

6. This proceeding shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with § 1.1206(b). In proceedings governed by § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda

summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.*, .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Procedural Matters

A. Initial Regulatory Flexibility Analysis

7. The Initial Regulatory Flexibility Analysis required by section 604 of the Regulatory Flexibility Act, 5 U.S.C. 604, is included in appendix C of the NPRM.

8. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this Notice of Proposed Rulemaking (NPRM). Written public comments are requested on this IRFA. Comments must be filed by the same dates as listed on the first page of the NPRM and must have a separate and distinct heading designating them as responses to this IRFA. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the **Federal Register**.

B. Need for, and Objectives of, the Proposed Rules

9. The NPRM seeks comment on proposals to implement provisions of the Middle Class Tax Relief and Job Creation Act of 2012 ("Public Safety Spectrum Act" or "Act") governing deployment of the Nationwide Public Safety Broadband Network (NPSBN) in the 700 MHz band.

10. The Public Safety Spectrum Act establishes the First Responder Network Authority (FirstNet) to oversee the construction and operation of the NPSBN as licensee of both the existing public safety broadband spectrum (763–769/793–799 MHz) and the spectrally adjacent D Block spectrum (758–763/788–793 MHz). The Act directs the Federal Communications Commission (FCC or Commission) to reallocate the D Block for public safety services, to license the D Block and the existing public safety broadband spectrum to FirstNet and to take other actions necessary to "facilitate the transition" of such existing spectrum to FirstNet. The Act gives each State the option to opt out of FirstNet's Radio Access Network (RAN) deployment within that State and conduct its own RAN deployment.

11. Proposals in the NPRM are intended to provide States and other interested parties with clarity and an opportunity to comment on the procedures that the Commission will establish for filing and review of State opt-out requests and associated alternative State plans, the content to be included in state opt-out filings with the Commission, and the evaluation process that the Commission will use to approve or disapprove State opt-out requests in accordance with the criteria specified in the Act.

C. Legal Basis

12. The proposed action is authorized under pursuant to sections 1, 4(i), 4(j), 301, 303, and 316 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 301, 303, 316, as well as title VI of the Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, 126 Stat. 156.

D. Description and Estimate of the Number of Small Entities To Which the Proposed Rules Will Apply

13. The RFA directs agencies to provide a description of, and, where feasible, an estimate of, the number of small entities that may be affected by the rules proposed herein. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. A "small business concern" is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration ("SBA"). Below, we further describe and estimate the number of small entity licensees and regulatees that may be affected by the rules changes we propose in this document.

14. As an initial matter, we observe that the Public Safety Spectrum Act does not contemplate that "small governmental jurisdictions" would be directly authorized to serve as operators of their own 700 MHz public safety broadband networks. Rather, the Act charges a single entity, FirstNet, with constructing, operating, and maintaining the NPSBN on a nationwide basis. Accordingly, the requirements the NPRM proposes or considers for the combined 700 MHz public safety broadband spectrum—in which FirstNet will operate on a nationwide basis—will not directly affect a substantial number of small entities. The absence of a direct effect on a substantial number of small entities suggests that it is not necessary to prepare a regulatory flexibility analysis in connection with these proposed requirements.

E. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

15. The NPRM seeks comment on when State Governors will be required to notify FirstNet, NTIA, and the Commission if they wish to opt out of the NPSBN. Specifically the NPRM proposes to require States electing to opt out of the NPSBN to file a notification with the Commission no later than 90 days after the date they receive electronic notice of FirstNet's final proposed plan for the State. The NPRM also seeks comment how notice should be provided and on whether an entity other than a State Governor, such as the Governor's designee should be permitted to complete this filing requirement.

16. The NPRM seeks comment on the Act's provision that States choosing to opt out have 180 days to "develop and complete" requests for proposals (RFPs). In particular, the NPRM seeks comment on what showing is sufficient to demonstrate that a State has "completed" its RFP within the 180-day period. The NPRM further proposes that, if a State notifies the Commission of its intention to opt out of the NPSBN, the State will have 180 days from the date it provides such notification to submit its alternative plan to the Commission. The NPRM proposes to treat a State's failure to submit an alternative plan within the 180-day period as discontinuing that State's opt out process and forfeiting its right to further consideration of its opt-out request. The NPRM seeks comment on what an opt-out State should be required to include in its alternative plan for the plan to be considered complete for purposes of the Commission's review.

17. The NPRM seeks comment on whether States should be required to file their alternative plans in PS Docket No. 16–269, and the scope and types of information that must be included in the submission. The NPRM also seeks comment on whether States should be allowed to file amendments or provide supplemental information to the plan once it is filed with the Commission and prior to the Commission's decision. Should Commission staff be permitted

to discuss or seek clarification of the alternative plan contents with the filer? If a plan is deemed sufficient for our purposes before a State awards a contract pursuant to its RFP, should the Commission condition approval on substantial compliance with the approved plan under the awarded contract, or should this be addressed by NTIA under its "ongoing" interoperability evaluation?

18. The NPRM also seeks comment on who should have access to and the ability to comment on State alternative plans. In this regard, the NPRM seeks comment on the extent to which State alternative plans may contain confidential, competitive, or sensitive information or information that implicates national security. Should State plans be treated as confidential, with public notice limited to identifying which States have elected to opt out and filed an alternative plan? If so, should the Commission require such filing, and should the public be given an opportunity to comment on them? If State plans were filed publicly, would the Commission's existing rules allowing parties to request confidential treatment for their filings provide adequate protection of sensitive information? Alternatively, given the likelihood of sensitive information and the limited scope of the Commission's review of State plans under section 6302(e)(3)(C)(i) of the Act, should the Commission limit the parties that are entitled to review and comment on such plans? Should comment be limited to specific issues?

19. The NPRM also seeks comment on whether FirstNet and/or NTIA should be allowed access and the ability to comment to the Commission on State plans within a defined comment period. Assuming that FirstNet and NTIA are afforded a right to comment on State plans, should States have the right to respond to such comments? What rights, if any, should States have to review or comment on alternative plans submitted by other States? What other procedures are appropriate for the Commission's review of such plans? How can the Commission most appropriately ensure that it has heard all "evidence pertinent and material to the decision"?

20. The NPRM proposes that each alternative plan submitted to the Commission should receive expeditious review. The NPRM proposes to establish a "shot clock" for Commission action on alternative plans to provide a measure of certainty and expedience to the process. The NPRM seeks comment on what an appropriate shot clock period would be.

21. The NPRM seeks comment on the standard against which alternative State plans will be evaluated, specifically with respect to the Act's requirements that alternative plans demonstrate: (1) that the State will be in compliance with the minimum technical interoperability requirements developed under section 6203, and (2) interoperability with the nationwide public safety broadband network.

22. Under the first prong, the NPRM seeks comment on the utilization of RAN-related requirements specified in the minimum technical interoperability requirements. Specifically, the NPRM proposes that review under this prong would include requirements (1)–(3), (7)–(10), (20)–(25), (29), (39), (41)–(42) from the Board Report, as documented in Appendix B of the NPRM.

23. Under the second prong, the NPRM proposes a broader view than the first prong in demonstrating "interoperability" with the NPSBN, but still limited to the RAN. In particular, the NPRM seeks comment on the role of the Commission to independently and impartially evaluate whether alternative plans comply with the interoperability-related requirements established by FirstNet, and suggests that the Commission does not have the ability to impose network policies or interoperability requirements on FirstNet.

24. The NPRM seeks comment on the view that if the Commission disapproves a plan, the opportunity for a State to conduct its own RAN deployment will be forfeited and FirstNet "shall proceed in accordance with its proposed plan for that State."

25. The NPRM seeks comment on the view that the Commission's approval of a State opt-out plan as meeting the interoperability criteria in ection 6302(e)(3)(C) of the Act would not create a presumption that the State plan meets any of the criteria that NTIA is responsible for evaluating under section 6302(e)(3)(D) of the Act.

26. The NPRM seeks comment on how the Commission should document its decisions to approve or disapprove State opt-out requests under the statutory criteria. Should it issue a written decision or order explaining the basis for each decision, or would it be sufficient to provide more limited notice of approval or disapproval in each case without a detailed explanation?

F. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

27. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof for small entities.

28. The proposed rules will not affect any small entities.

G. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

29. None.

H. Paperwork Reduction Act of 1995 Analysis

30. This NPRM seeks comment on potential new information collection requirements. If the Commission adopts any new information collection requirements, the Commission will publish a document in the **Federal Register** inviting the public to comment on the requirements, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501–3520). In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might "further reduce the information collection burden for small business concerns with fewer than 25 employees."

Ordering Clauses

31. Accordingly, it is ordered that, pursuant to sections 1, 4(i), 4(j), 301, 303, and 316 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 301, 303, 316, as well as title VI of the Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, 126 Stat. 156, the Notice of Proposed Rulemaking is hereby adopted.

32. It is further ordered that pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on the NPRM on or before October 21, 2016 and reply comments on or before November 21, 2016.

List of Subjects in 47 CFR Part 90

Radio.

Federal Communications Commission.

Marlene Dortch,

Secretary.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 90 as follows:

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

■ 1. The authority citation for part 90 continues to read as follows:

Authority: Sections 4(i), 11, 303(g), 303(r) and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r) and 332(c)(7), and Title VI of the Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. 112–96, 126 Stat. 156.

■ 2. Revise § 90.532 to read as follows:

§ 90.532 Licensing of the 758–769 MHz and 788–799 MHz Bands; State opt-out election and alternative plans.

(a) *First Responder Network Authority license and renewal.* Pursuant to section 6201 of the Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, 126 Stat. 156 (2012), a nationwide license for use of the 758–769 MHz and 788–799 MHz bands shall be issued to the First Responder Network Authority for an initial license term of ten years from the date of the initial issuance of the license. Prior to expiration of the term of such initial license, the First Responder Network Authority shall submit to the Commission an application for the renewal of such license. Such renewal application shall demonstrate that, during the preceding license term, the First Responder Network Authority has met the duties and obligations set forth under the foregoing Act. A renewal license shall be for a term not to exceed ten years.

(b) *State election to opt out of the First Responder Network Authority Nationwide Network.* No later than 90 days after receipt of notice from the First Responder Network Authority under section 6302(e)(1) of the Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, 126 Stat. 156 (Spectrum Act), any State governor electing to opt out and conduct its own deployment of a State radio access network pursuant to section 6302(e)(2)(B) of the Middle Class Tax Relief and Job Creation Act of 2012 shall file a notification of its election with the Commission. Such notification shall also certify that the State has notified the First Responder Network Authority and the National Telecommunications and Information Administration of its election.

(c) *Filing of alternative State plans by States electing to opt out.* No later than 180 days after filing notice of a State's election with the Commission under paragraph (b) of this section, the State Governor or the Governor's designee shall file an alternative plan with the Commission for the construction, maintenance, operation and improvements of the State radio access network. Such a plan shall demonstrate:

(1) That the State will be in compliance with the minimum technical interoperability requirements developed under section 6203 of the Middle Class Tax Relief and Job Creation Act of 2012; and

(2) Interoperability with the nationwide public safety broadband network.

[FR Doc. 2016–22714 Filed 9–20–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2016–0096; 4500030115]

Endangered and Threatened Wildlife and Plants; 90-Day Findings on 10 Petitions; Correction

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Correction.

SUMMARY: On September 14, 2016, we, the U.S. Fish and Wildlife Service (Service), published a document in the **Federal Register** announcing 90-day findings on 10 petitions to list, reclassify, or delist fish, wildlife, or plants under the Endangered Species Act of 1973, as amended. That document included a not-substantial finding for the Fourche Mountain salamander. The finding contained an incorrect range State, Arizona, for this species; the correct range State is Arkansas. With this document, we correct that error. If you sent a comment previously, you need not resend the comment.

DATES: Correction issued on September 21, 2016. To ensure that we will have adequate time to consider submitted information during the status reviews, we request that we receive information no later than November 14, 2016.

FOR FURTHER INFORMATION CONTACT: Andreas Moshogianis, (404) 679–7119. If you use a telecommunications device for the deaf, please call the Federal Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 14, 2016 (81 FR 63160), in FR Doc. 2016–22071, on page 63162, in the second column, correct the State under *Species and Range* from "Arizona" to "Arkansas".

Dated: September 14, 2016.

Tina A. Campbell,

Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.

[FR Doc. 2016–22558 Filed 9–20–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2016–0103; 4500030113]

RIN 1018–AZ02

Endangered and Threatened Wildlife and Plants; Endangered Species Status for Sonoyta Mud Turtle

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Sonoyta mud turtle (*Kinosternon sonoriense longifemorale*), a native subspecies from Arizona in the United States and Sonora in Mexico, as an endangered species under the Endangered Species Act (Act). If we finalize this rule as proposed, it would extend the Act's protections to this subspecies. The effect of this regulation will be to add this subspecies to the List of Endangered and Threatened Wildlife.

DATES: We will accept comments received or postmarked on or before November 21, 2016. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by November 7, 2016.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R2–ES–2016–0103, which is the docket number for this rulemaking. Then, in the Search panel on the left

side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on "Comment Now!"

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R2–ES–2016–0103; U.S. Fish & Wildlife Service Headquarters, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see *Public Comments* below for more information).

FOR FURTHER INFORMATION CONTACT: Steve Spangle, Field Supervisor, U.S. Fish and Wildlife Service, Arizona Ecological Services Field Office, 9828 North 31st Ave. #C3, Phoenix, AZ 85051–2517, by telephone 602–242–0210 or by facsimile 602–242–2513. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if a species is determined to be an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within one year. Critical habitat shall be designated, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designations and revisions of critical habitat can only be completed by issuing a rule. We will be providing a proposal to designate critical habitat for the Sonoyta mud turtle under the Act in the near future.

Our proposed determination. This document proposes the listing of the Sonoyta mud turtle (*Kinosternon sonoriense longifemorale*) as an endangered species. The Sonoyta mud turtle is currently a candidate species for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing regulation has been precluded by other higher priority listing activities. This proposed rule reassesses all available information regarding status of and threats to the Sonoyta mud turtle.

The basis for our action. Under the Act, we can determine that a species is an endangered or threatened species based on any of five factors after taking into account those efforts to protect such species: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence. We have determined that Factors A (reduction or loss of water availability; reduction or loss of riparian habitat components; reduction or loss of invertebrate prey), C (nonnative predators), and E (climate change) are and will continue to affect the populations of Sonoyta mud turtle. The Act defines the term "species" to include any subspecies of fish or wildlife or plants.

We will seek peer review. We will seek comments from independent specialists to ensure that our designation is based on scientifically sound data, assumptions, and analyses. We will invite these peer reviewers to comment on our listing proposal. Because we will consider all comments and information received during the comment period, our final determinations may differ from this proposal.

To provide the necessary and most up-to-date information and background on which to base our determination, we completed a Species Status Assessment Report for the Sonoyta mud turtle (SSA Report; Service 2016, entire), which is available online at *http://www.regulations.gov,* Docket No. FWS–R2–ES–2016–0103. The SSA Report documents the results of the comprehensive biological status review for the Sonoyta mud turtle and provides an account of the subspecies' overall viability through the forecasting of the condition of surviving populations into the future (Service 2016, entire). In the SSA Report, we summarized the relevant biological data, described the past, present, and likely future risk factors (causes and effects), and conducted an analysis of the viability of the subspecies. The SSA Report provides the scientific basis that informs our regulatory decision regarding whether this subspecies should be listed under the Act. This decision involves the application of standards within the Act, its implementing regulations, and Service policies (see Finding). The SSA Report contains the risk analysis on which this finding is based, and the following discussion is a summary of the results and conclusions from the SSA Report. Species experts and appropriate agencies provided input into the development of the SSA Report. Additionally, we will invite peer reviewers to provide a review of the SSA Report.

Information Requested

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from the public, other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The Sonoyta mud turtle's biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

(5) Information related to climate change within the range the Sonoyta mud turtle and how it may affect the species' habitat.

(6) The reasons why areas should or should not be designated as critical habitat as provided by section 4 of the Act (16 U.S.C. 1531 *et seq.*).

(7) The following specific information on:

(a) The amount and distribution of habitat for the Sonoyta mud turtle.

(b) What areas, that are currently occupied and that contain the physical and biological features essential to the conservation of the Sonoyta mud turtle, should be included in a critical habitat designation and why.

(c) Special management considerations or protection that may be needed for the essential features in potential critical habitat areas, including managing for the potential effects of climate change.

(d) What areas not occupied at the time of listing are essential for the conservation of the species and why.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Also please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is a threatened or endangered species must be made "solely on the basis of the best scientific and commercial data available."

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Arizona Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Public Hearing

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we have sought the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our listing determination is based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise in the Sonoyta mud turtle's biology, habitat, physical or biological factors, or threats. We are inviting comment from the peer reviewers during this public comment period.

Previous Federal Actions

We identified the Sonoyta mud turtle as a candidate species with a listing priority number (LPN) of 3 in the annual Candidate Notice of Review (CNOR) on September 19, 1997 (62 FR 49398). Candidates are those fish, wildlife, and plants for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing regulation is precluded by other higher priority listing activities. We reaffirmed the Sonoyta mud turtle's candidate status in subsequent annual CNORs (64 FR 57534, October 25, 1999; 66 FR 54808, October 30, 2001; 67 FR 40657, June 13, 2002; 69 FR 24876, May 4, 2004; 70 FR 24870, May 11, 2005; 71 FR 53756, September 12, 2006; 72 FR 69033, December 6, 2007; 73 FR 75175, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; and 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; and 80 FR 80585, December 24, 2015). In 2012, based on a change in the timing of the threat from the reduction of surface water to non-imminent, we changed the Sonoyta mud turtle LPN from 3 to 6, which reflects a subspecies with threats that are non-imminent and high in magnitude. We retained an LPN of 6 through the latest CNOR.

On May 4, 2004, we received a petition from the Center for Biological Diversity and others (petitioners) requesting the Service to list 225 plants and animals as endangered under the Endangered Species Act, as amended (16 U.S.C. 1531 *et seq.*), including the Sonoyta mud turtle and to designate critical habitat. On September 9, 2011, the Service entered into two settlement agreements regarding species on the candidate list at that time (Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)). This proposed rule fulfills that requirement of those settlement agreements for the Sonoyta mud turtle. We will also be providing a proposal to designate critical habitat for the Sonoyta mud turtle under the Act in the near future.

Background

The Act directs us to determine whether any species is an endangered species or a threatened species because of any of the five enumerated factors, and taking into account the effect of conservation measures. The Act defines the term "species" to include any subspecies of fish or wildlife or plants. We completed a comprehensive evaluation of the taxonomy, life history, ecology, and biological status of the Sonoyta mud turtle *(Kinosternon sonoriense longifemorale),* and we provide a thorough assessment of the species' overall viability in the SSA Report (Service 2016, pp. 4–5; available at *http://www.regulations.gov* and the Arizona Ecological Services Office *https://www.fws.gov/southwest/es/arizona/*).

Summary of Biological Status and Threats

The Sonoyta mud turtle is one of two recognized subspecies of Sonora mud turtle (*Kinosternon sonoriense*) and has been differentiated from the other subspecies based on morphometric (shape or form of organism) analysis of shell measurements and mitochondrial DNA analysis (Iverson 1981, p. 62; Rosen 2003, entire; Rosen *et al.* 2006, entire). The other subspecies, *K. s. sonoriense,* is commonly referred to as Sonora mud turtle. Figure 1 below depicts the location of each subspecies. The Sonoyta mud turtle is a dark, medium-sized freshwater turtle with a mottled pattern on the head, neck, and limbs. The Sonoyta mud turtle is an isolated, native endemic (found in certain areas) of southern Arizona and northern Sonora, Mexico. At Quitobaquito, annual survivorship of adults (7–12 years old) and juveniles (<7 years old) has been estimated by Rosen and Lowe (1996, p. 23) and Riedle *et al.* (2012, p. 187) with similar results. Male survivorship ranged from 0.83–0.95, female survivorship ranged from 0.85–

0.95, and juvenile survivorship was lower than adult survivorship with a gradual transition to higher survivorship as turtles moved towards adulthood (Riedle *et al.* 2012, p. 187; Rosen and Lowe 1996, p. 23).

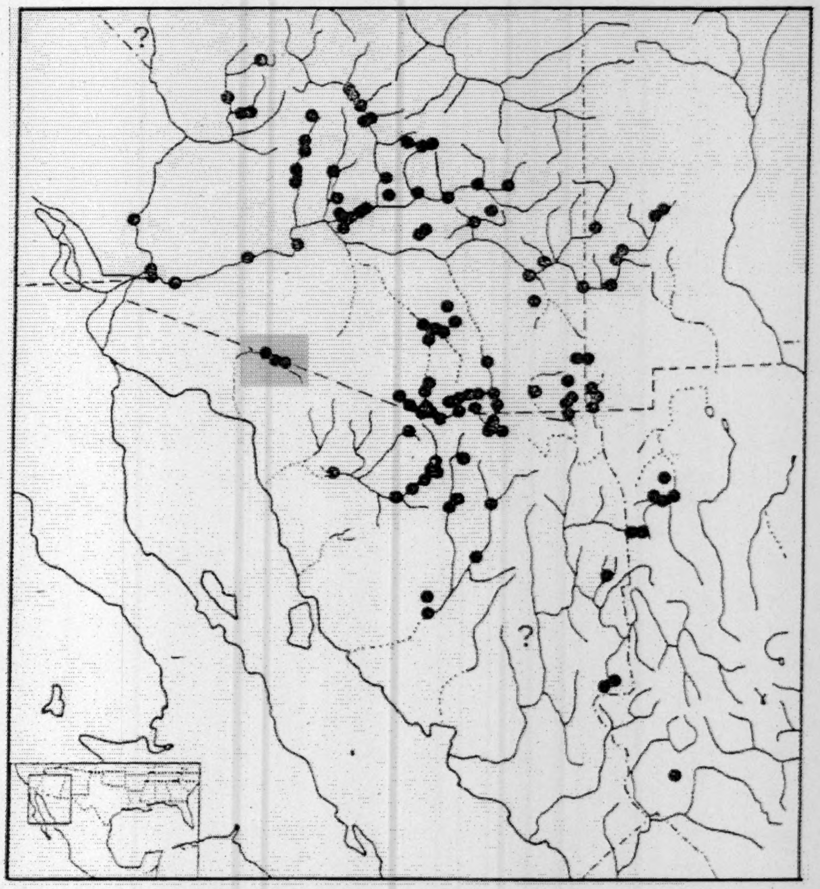


Figure 1.—Entire species range is shown above with Sonoyta mud turtle subspecies depicted in gray box (Iverson 1992, p. 235). The black dots outside of the gray box are known occurrences of the other subspecies, Sonora mud turtle.

Sonoyta mud turtles occur in areas of an arid environment that commonly experience drought and extreme heat (ambient temperatures can exceed 45 degrees Celsius (°C) (113 degrees Fahrenheit (°F))) and in order to survive and complete life-history functions need both perennial sources of water with aquatic vegetation and riparian areas with moist soil. Sonoyta mud turtles spend most of their time in water because water is essential to survival of individuals, as it provides food and prevents desiccation. Water is also needed to provide moisture for soil in riparian areas needed for nesting and estivation (spending time in a prolonged state of torpor or dormancy) during drought. Lastly, water with aquatic vegetation is needed to support invertebrate prey and provide shelter from predators. Sonoyta mud turtles are primarily opportunistic carnivores feeding on a variety of invertebrates that are on the bottom of ponds and streams or attached to submerged vegetation. In habitat with poor invertebrate fauna they will also feed on small vertebrates, carrion, and plants (Hulse 1974, pp. 197–198; Lovich *et al.* 2010, pp. 135–136; Rosen 1986, pp. 14 & 31; Rosen and Lowe 1996a, pp. 32–35; Stanila *et al.* 2008, p. 345).

Sonoyta mud turtles are found in stream channels, and natural and manmade ponds. Water in ponds is supplied by either springs or human waste-water effluent. Aquatic habitat in ponds and stream channels is usually shallow (to 2 meters (m) (7 feet (ft)), with a rocky or sandy bottom and aquatic, emergent vegetation. Hatchlings, juveniles, and subadults prefer shallow water with dense aquatic vegetation and overhanging vegetation along the stream channel or pond margin that provides foraging opportunities as well as protection from predators. Adults prefer water with complex structure including overhanging vegetation along the stream channel or pond margin but also deeper sections of ponds where they forage for benthic invertebrates along the bottom.

Terrestrial habitat of Sonoyta mud turtles is characterized by riparian vegetation with moist soil that surrounds a pond or lines a stream channel, and occurs along the banks of ponds and streams, as well as in intermittently dry sections of the stream channel itself. Sonoyta mud turtles in dry or low surface water reaches will either travel along intermittent dry sections of a stream channel to find water or they will estivate. Riparian vegetation provides some level of protection from predators while turtles are out of the water, and it also creates a microclimate that supports moist soil. Moist soil is needed to prevent desiccation of adults and juveniles while traveling between wetted sites or during estivation. Terrestrial estivation sites consist of depressions under vegetation, soil, or organic matter; in rock crevices; or in soil burrows under overhanging banks of streams or ponds. Sonoyta mud turtles can endure lack of surface water for a short time by estivating, but prolonged and recurrent estivation will reduce fitness and increase mortality over the long term. Riparian vegetation and corresponding moist soil are also needed for nest sites. In mid to late July through September, females leave the water briefly to lay eggs in terrestrial nests that maintain some level of moisture such as vegetation litter, soil burrows, or possibly even in rock crevices. The SSA Report has more detailed discussion of our evaluation of the biological status of the Sonoyta mud turtle and the influences that may affect its continued existence.

The Sonoyta mud turtle was historically found only in the Rio Sonoyta basin in Arizona and Sonora, Mexico (Figure 3.1.1.a. in the SSA Report). There were likely four populations of the Sonoyta mud turtle distributed throughout the Rio Sonoyta basin in Arizona and Sonora (SSA Report Figure 3.1.1.b.). One population was located at Quitobaquito in southern Arizona in an area that is now within the Organ Pipe Cactus National Monument. This population is north of the Rio Sonoyta, but fossil spring deposits to the west of Quitobaquito Springs indicate that, during floods or in times of greater natural flow, water filled an adjacent wash and likely established a connection to the Rio Sonoyta (Miller and Fuiman 1987, p. 603). The other three populations occurred in distinct perennial reaches of the Rio Sonoyta in Sonora, Mexico, just south of the U.S.-Mexico border. These included the Papalote reach, Santo Domingo reach, and Sonoyta reach of Rio Sonoyta. The Rio Sonoyta probably flowed continuously for short periods during the wet season providing connectivity for mud turtles allowing for immigration and emigration and then retracted during the dry season. This assumption is based on our understanding of the historical literature of hydrological conditions in the period 1854–1936 (Rosen et al. 2010, p. 146). These three distinct perennial reaches of the Rio Sonoyta (Papalote reach, Santo Domingo reach, and Sonoyta reach) together likely provided 19–27 km (11.8–16.8 mi) of stream habitat for the Sonoyta mud turtle (Table 1.). This amount is estimated from measuring maps in the historical literature of hydrological conditions in the period 1854–1936 (Rosen et al. 2010, p. 146). The best available commercial and scientific data does not indicate any additional populations.

Currently, there are five extant populations. The Quitobaquito Springs population in Organ Pipe Cactus National Monument, Arizona, is extant (National Park Service (NPS) 2015, p. 1). Populations in the Papalote reach and Sonoyta reach (now Xochimilco reach) of Rio Sonoyta are extant, but perennial water flow in their reaches are reduced. The historical population in the Santo Domingo reach of the Rio Sonoyta is now likely extirpated due to loss of perennial surface water (P. Rosen, pers. comm., 2016; Rosen 3004, pp. 4–5). The Sonoyta sewage lagoon and Quitovac populations in Mexico were historically unknown and recently found by Knowles et al. 2002 (p. 74) investigating potential new turtle habitats in and around the Rio Sonoyta basin. Turtles were reported in the Sonoyta sewage lagoon in October 2001 (Knowles et al. 2002, p. 4); turtles either dispersed there from the upstream Xochimilco reach or were released by humans soon after the sewage lagoon came into operation in 1994. The Sonoyta sewage lagoon population is in the town of Sonoyta adjacent to the Rio Sonoyta. The Sonoyta sewage lagoon is a settling pond for raw wastewater from the town of Sonoyta. Sonoyta mud turtles were also discovered in spring runs and ponds at Quitovac in March 2002 (Knowles et al. 2002, p. 72). Quitovac is located about 40 km (25 mi) southwest of the town of Sonoyta and outside of the Rio Sonoyta basin, in the Rio Guadalupe basin. It is unclear when this population was established, and geography suggests that the turtle population may have resulted from human introduction of turtles.

The perennial water supporting all five turtle populations has been reduced, and all populations are small and isolated. Discharge from Quitobaquito springs has diminished by 42 percent over the past 35 years with 5,500 cubic feet (cf)/day average discharge measured in the period 1981–1992 down to 3,157 cf/day measured from 2005–present (Carruth 1996, pp. 13, 21; Peter Holm, pers. comm., 2016). Thus far, declining spring flow has been associated with < 30 centimeters (cm) (12 inches (in)) of surface water level decline at the pond, the depth of which ranges from 81 to 94 cm (32 to 37 inches). Today, the five Sonoyta mud turtle populations are isolated from one another even more than they used to be historically because the lengths of the distinct perennial reaches in the Rio Sonoyta have contracted. The perennial waters in these reaches have decreased by 80 to 92 percent from 19–27 km (11.8–16.8 mi) historically to approximately 1.5–5.5 km (0.9–3.4 mi) currently (Table 1. Historical and Current Population Data below, and Figure 3.1.1 of the SSA Report). Periodic movement between populations in the Rio Sonoyta basin may occur during periods of high rainfall, but the extent of immigration and emigration of turtles is unknown. However, we assume that movement among populations is rare to limited due to distances between populations coupled with limited hydrological connection. The Quitovac population is outside of the Rio Sonoyta watershed, in the Rio Guadalupe basin, and has no present-day hydrological connection to the Rio Sonoyta.

Table 1 lists the status and condition of each population. We believe that the historical locations of the Sonoyta mud turtle occurred in the areas of the Rio Sonoyta basin that maintained perennial surface water via springs fed by ground water and that these locations may no longer have reliable water to support mud turtles (Paredes-Aguilar and Rosen 2003, p. 2; Rosen *et al.* 2010, p. 155).

TABLE 1—HISTORICAL AND CURRENT POPULATION DATA OF THE SONOYTA MUD TURTLE

Location	Land ownership	Abundance		Distribution			Status
		Historical	Current	Historical	Current		
				Perennial stream km (mi)	Perennial stream km (mi)	Area ha (ac)	
AZ							
Quitobaquito	Organ Pipe Cactus National Monument.	Several hundred in 1950s.	2015 = 141 ± 25 Avg = 110 [1]	unknown	0.244 (−0.15)	<0.27 (0.67)	Extant.
Mexico							
Rio Sonoyta:							
Papalote Reach (or the Agua Dulce).	Mexican NPS, Rio Sonoyta, Pinacate Biosphere Reserve.	unknown	2003 = >100, low density. Now = unknown	5–6 (3.1–3.7)	1.5 to 3 (0.9–1.9)	pool size 2–4.5 m^2 (22–48 ft^2)	Extant.
Santo Domingo	Ejido Josefa Ortiz de Dominguez.	unknown	0	4–6 (2.5–3.7)	0		Extirpated.
Sonoyta Reach (reduced to Xochimilco Reach).	Town of Sonoyta	unknown	2002 = ~345 Now = unknown	10–15 (6.2–9.3)	0 to 2.5 (0–1.6)	pool size 10–48 m^2. (107–516 ft^2)	Extant.
Rio Sonoyta Total.				19–27 (11.8–16.8).			
Sonoyta Sewage Lagoon.	Town of Sonoyta	N/A	N/A	N/A	N/A	>5 (>12.3)	Extant.
Quitovac	Quitovac y su anexo el Chujubabi.	N/A	2002 = ~200	N/A	N/A	>1 (>2.5)	Extant.

[1] Estimates from Quitobaquito include adults only; no young-of-the-year are included. This average is from 2001 to 2015.

For the Sonoyta mud turtle to maintain viability, its populations, or some portion of its populations, must be resilient enough to withstand stochastic events such as fluctuations in water levels, habitat modification, and introduction of nonnative predators. In a highly resilient Sonoyta mud turtle population, turtles are able to complete their life functions and breeding is successful enough to maintain a population that is able to withstand stochastic events. Influencing these population factors are elements of Sonoyta mud turtle habitat (surface water availability, amount of riparian habitat and benthic invertebrates, and lack of nonnative predators) that determine whether survivorship among age classes is achieved in Sonoyta mud turtle populations, thereby increasing the resiliency of populations. Population resiliency categories for the Sonoyta mud turtle are described in Table 3.3.1. of the SSA Report, and habitat factors used to develop these resiliency levels are discussed below and outlined in Table 3.4.2. of the SSA Report. As discussed below, water is the primary limiting factor, and, therefore, water drives the condition of each population.

Representation in the form of genetic or ecological diversity is important to maintain the Sonoyta mud turtle's capacity to adapt to future environmental changes. Genetic investigations (Rosen 2003, pp. 8–13; Rosen *et al.* 2006, p. 10) indicate the subspecies exhibits some level of genetic diversity among populations at Quitobaquito, in the Papalote reach and the Xochimilco reach of the Rio Sonoyta, and at Quitovac. The population in the Sonoyta sewage lagoon was not sampled, so we have no information on genetics of this population. Exchange of genetic material between Quitobaquito and populations along the Rio Sonoyta is unlikely due to lack of hydrological connection. Exchange of genetic material among populations of the Rio Sonoyta is likely a rare event limited to instances when a mud turtle may move during the wet season if there are prolonged periods of precipitation that cause a high flow event along the Rio Sonoyta or connects these populations by providing stepping stones of wetted habitat through which mud turtles could move or disperse.

The Sonoyta mud turtle historically occupied habitat in two ecological settings including cienegas (a spring that is usually a wet, marshy area at the foot of a mountain, in a canyon, or on the edge of a grassland where ground water bubbles to the surface) and streams, both supported by ground water via springs. Currently, there are still populations within stream habitat but all the cienegas have either dried completely or been modified from their natural state. There are also two manmade impoundments that were created to capture spring flow that now support Sonoyta mud turtles. Currently, the Sonoyta mud turtle exhibits genetic and ecological diversity. Maintaining representation in the form of genetic or ecological diversity is important to maintain the Sonoyta mud turtle's capacity to adapt to future environmental changes. The loss of Quitobaquito, Quitovac, and either Rio Sonoyta Papalote or Rio Sonoyta Xochimilco populations would reduce the representation for the species.

Redundancy describes the ability of a species to withstand catastrophic events. Measured by the number of populations, their resiliency, and their distribution (and connectivity), redundancy gauges the probability that the species has a margin of safety to withstand or can bounce back from catastrophic events (such as a rare destructive natural event or episode involving one or more populations). The Sonoyta mud turtle needs multiple resilient populations spread over their range distributed in such a way that a catastrophic event will not result in the loss of all populations. Currently four of the populations are spread throughout a small area of the Rio Sonoyta basin, and one population is in the northern part of the Rio Guadalupe basin. It is possible that a catastrophic event such as severe drought could impact three of the five populations—Papalote reach, Xochimilco reach, and Quitobaquito. Conversely, catastrophic events such as disease would not likely impact multiple populations since the hydrological connection among populations is limited or nonexistent. While there could be rare or limited movement of individuals between populations, all populations are isolated in terms of one population being able to repopulate another should one be lost due to a catastrophic event.

The Service evaluated the stressors affecting the conservation status of the Sonoyta mud turtle, which include water loss, loss of riparian habitat, amount of invertebrate prey, presence of nonnative species, and land management activities incompatible with maintaining needed habitat (such as dredging). Of these stressors, water loss caused by drought and ground water pumping, both of which are exacerbated by climate change, and changes to wastewater infrastructure are the primary activities impacting the Sonoyta mud turtle. The other stressors to the Sonoyta mud turtle include the loss of invertebrate prey and presence of nonnative species. These stressors can be additive in terms of effects to populations that are already stressed by water loss. The following is a summary of these stressors affecting the Sonoyta mud turtle. These stressors are described in detail in Appendix A of the SSA Report.

Ground water pumping impacts the amount of surface water in habitats used by Sonoyta mud turtles because the perennial sections of the Rio Sonoyta as well as the pond at Quitobaquito and Quitovac are supplied by ground water. As with all streams, the Rio Sonoyta exists in an area where runoff has concentrated into a definable channel. In most of the Rio Sonoyta, the channel cuts into dry soils, so that flow is ephemeral and only in response to precipitation. In the Papalote and Xochimilco reaches of the Rio Sonoyta where Sonoyta mud turtles live, the defined channel intersects regional ground water held in storage, the ground water saturates streamside channel bottom soils, and water is discharged to the stream. In a hypothetical, unaffected system, equilibrium exists so that recharge and discharge volumes of water are equal. When pumping occurs in such a ground water system, it alters this equilibrium so that less water is available for discharge to the stream and springs and reduces the amount of surface water available to the Sonoyta mud turtle.

Ground water can also reach the ground surface outside of a stream channel via springs like those that supply water to habitats of the Sonoyta mud turtle at Quitobaquito and Quitovac. Quitobaquito Springs is likely supplied by ground water but is considered somewhat isolated from the regional aquifer in the Sonoyta Valley (Carruth 1996, pp. 14, 18). It is possible that there is a connection between the two systems so that Quitobaquito Springs could experience a delayed effect by an increase in ground water drawdown occurring in Mexico (Carruth 1996, p. 21). Discharge from Quitobaquito Springs has diminished by 42 percent over the past 35 years with 5,500 cf/day average discharge measured from 1981–1992 down to 3,157 cf/day measured from 2005–present (Carruth 1996, pp. 13, 21; Peter Holm, pers. comm., 2016). Reasons for this decrease are unknown.

Human demands on ground water in the Rio Sonoyta basin include agriculture and municipal use to support a growing population, both of which are almost wholly dependent on ground water. Irrigated agriculture is widespread in the Rio Sonoyta Valley, and continued development in the towns of Sonoyta and Lukeville is placing increased demands on limited ground water availability. Potential ground water use in the Rio Sonoyta watershed is greater than the estimated recharge rate. Based on total number of wells installed along the Rio Sonoyta, existing capacity for wells to withdraw water is six times the ground water recharge (Pearson and Connor 2000, p. 388). Although we do not have any recent observations of actual ground water use, we can assume that ground water pumping currently exceeds recharge based on negative trends of depth to ground water measured from 1992 to 2010 at Organ Pipe Cactus National Monument in wells that are close to the agricultural zone of Sonoyta, Sonora (OPCNM 2011, p. 8).

At Quitovac, there are five springs that provide water to the impounded pond. The pond at Quitovac is used for watering small numbers of livestock and irrigating fruit trees (Aguirre and Rosen 2003, p. 11; USFWS files). One of the five springs at Quitovac was not flowing into the pond during a visit to the site in 2015 (D. Duncan, pers. obs., 2015). There has also been gold mining in the area surrounding Quitovac, and mine exploration and development continue, all of which require water. In addition, surface water diversion for agriculture has occurred in the past and is likely to continue into the future. The Quitovac population is in the Rio Guadalupe basin and, therefore, not likely affected by ground water pumping in the Rio Sonoyta. While ground water pumping could occur in this basin in the future, we currently have no information indicating the likelihood. Land management actions, such as dredging, also impact the Quitovac population. Partial dredging of the pond has occurred at least twice (Nabhan *et al.* 1982, p. 130; Nabhan 2008, p. 252; USFWS files). During a visit to the site on June 3, 2015, after the pond and spring heads had been completely excavated by dredging, only a single turtle with a damaged shell was found at the spring head (D. Duncan, pers. obs., 2015).

The surface water necessary for habitat of the subspecies generally is fed by ground water recharge. This recharge comes from infiltration of precipitation along mountain fronts and in ephemeral channels. However, drought conditions that have persisted for the past 20 years have likely contributed to decreased ground water recharge in the Rio Sonoyta basin and Rio Guadalupe basin. Decreased precipitation and increased evaporation related to increased duration of drought conditions have contributed to reduced surface water available to support the subspecies at all population sites. Climate model projections predict a shift to increasing dryness in the Southwest as early as 2021–2040 (Seager *et al.* 2007, p. 1181). Streamflow is predicted to decrease in the Southwest even if precipitation were to increase moderately (Nash and Gleick 1993, State of New Mexico 2005, Hoerling and Eischeid 2007) because warmer surface air temperatures lead to increased evaporation, increased evapotranspiration, and decreased soil moisture. These three factors would lead to decreased streamflow even if precipitation increased moderately (Garfin 2005, Seager *et al.* 2007). The effect of decreased streamflow is that streams become smaller, intermittent, or dry, and thereby reduce the amount of habitat available for Sonoyta mud turtles. A smaller stream is affected more by air temperature than a larger one, exacerbating the effects of both warm and cold air temperatures (Smith and Lavis 1975). Although Sonoyta mud turtles evolved in an extremely arid climate and have survived drought in the past, it is anticipated that a prolonged, intense drought would affect all populations, in particular those occupying the Rio Sonoyta, which is likely to become entirely ephemeral.

Habitat for the subspecies requires riparian vegetation, which is also dependent on surface water and ground water recharge. When ground water discharge is of sufficient volume to saturate streamside areas, riparian vegetation develops. This occurrence also extends to manmade ponds created to capture ground water discharge. The extent and persistence of this vegetation depends on the depth to ground water. In the case of the perennial sections of the Rio Sonoyta as well as the ponds at Quitobaquito and Quitovac, riparian vegetation has established where its root systems can reach the alluvial ground water. The use of water by the riparian vegetation (evapotranspiration) is itself a discharge of ground water, and can even affect surface flow in the adjacent stream or surface level in a pond. Because ground water extraction in the Rio Sonoyta basin continues to reduce depth to ground water, riparian vegetation has likely been reduced in the Rio Sonoyta, and streamside areas are now occupied by drought-tolerant plants, which generally lack the same ecological value of riparian vegetation.

Riparian vegetation is associated with increased ecological site conditions; organic matter produced by plants is a major contributor to soil development, structure, and moisture. The below-ground component of riparian vegetation further enhances floodplain and bank water storage because root growth, and subsequent root decay, creates conditions that increase rates of infiltration of rainwater and floodwater, thereby enhancing ground water recharge and base-flow replenishment. Riparian vegetation, despite its own water use, also moderates the direct evaporation of water from a stream or pond. Open water in Sonoyta mud turtle habitats likely exhibits relatively high evaporation compared to areas shaded by riparian overstory (Goodrich *et al.* 2000, pp. 292–293). Riparian vegetation surrounding water features provides essential habitat for all life stages of turtles. As riparian vegetation dies due to declining ground water, the physical and biological processes are reversed and a cascade of interconnected impacts begins. Dead trees decompose and no longer stabilize floodplain soils, which are then readily eroded away. The loss of floodplain soils and their ability to store flood waters reduces the gradual release of post-flood infiltrated water back to the stream, further reducing surface flows. Reductions in riparian habitat will also decrease subsurface moisture needed for nesting sites; drought refuge for hatchlings, juvenile and adult turtles; and shelter from large flooding events for juvenile and adult turtles. Decreased riparian vegetation will lead to deterioration of the microclimate that provides soil moisture to nest sites and burrows. (See Section 4.2 and Appendix A of the SSA Report).

In addition to loss of habitat associated with ground water pumping and drought in the Rio Sonoyta basin, changes to wastewater infrastructure in the town of Sonoyta have reduced surface water available in the Xochimilco reach of the Rio Sonoyta, but increased habitat for the subspecies in the Sonoyta sewage lagoon. Most of the wastewater that used to be discharged directly into the Xochimilco reach and provided a constant source of surface water that maintained perennial flow in this reach is now redirected to the Sonoyta sewage lagoon. Wastewater runoff is now likely limited to individual homesteads. Consequently, surface water available for Sonoyta mud turtles is greatly reduced in the Xochimilco reach of the Rio Sonoyta. It is likely that there is always a small pool of water in or near the dam site at Xochimilco, either from springs or urban wastewater from individual homesteads atop the arroyo wall. When wastewater that used to contribute surface water to the Xochimilco reach was redirected to the Sonoyta sewage lagoon, the amount of perennial water for Sonoyta mud turtles increased at the lagoon.

Sonoyta mud turtles continue to persist at the Sonoyta sewage lagoon, and this site is not subject to effects of ground water withdrawal and drought due to a consistent inflow of wastewater. The Sonoyta sewage lagoon is within the floodplain of the Rio Sonoyta, and might contribute some level of recharge to the Rio Sonoyta basin through seepage and outflow. There is a high likelihood that the sewage lagoon in the town of Sonoyta will be replaced by a new wastewater treatment plant about 2.4 km (1.5 mi) northwest of the existing sewage lagoon in the next few years. Efforts will be made to translocate as many Sonoyta mud turtles as possible to the new wastewater facility from the sewage lagoon; however, it is unknown what amount this will be. The new wastewater treatment plant will serve an additional 35 percent of the town of Sonoyta's residences and will, therefore, be larger overall. However, the habitat available to Sonoyta mud turtles will be reduced by more than 75 percent. There will be a greater number of lagoons at the new wastewater treatment plant, but only one will be unlined and provide habitat for the Sonoyta mud turtle. Lining precludes the development of habitat for Sonoyta mud turtles including aquatic and riparian vegetation (See Figure 3.2.1 of the SSA Report). This unlined pond will provide less than 25 percent of the habitat that is currently present at the Sonoyta sewage lagoon.

Effluent flowing through the new wastewater treatment facility will be discharged into the Rio Sonoyta. This activity could improve recharge of ground water and create perennial flow in the river immediately downstream of the new wastewater treatment plant, which in turn would provide additional habitat to the subspecies, although the extent is unknown. Based on the persistence of turtles at the Sonoyta sewage lagoon and increased wastewater volume to the new wastewater treatment plant, we would expect that turtles at the new wastewater treatment plant would also persist. Overall, wastewater from the town of Sonoyta will continue to provide a perennial water source that should continue to support one population of the Sonoyta mud turtle; however, since the available habitat is reduced by more than 75 percent, the population size will likely be reduced.

Reduced surface water and associated decrease in riparian vegetation, regardless of the cause, shrinks overall habitat amount and quality causing crowding and increased competition for limited resources (Stanila 2009 p. 45). Lack of surface water for a short time outside the typical dry season may be endured by individual Sonoyta mud turtles periodically, but multiple years without sufficient perennial water will reduce fitness and increase mortality. Sonoyta mud turtles in drying pond habitats or low surface water reaches will burrow in banks to escape desiccation for a short period of time. After time, burrows themselves may become too dry, turtles will lose fat reserves due to lack of foraging opportunity, females may not have viable eggs due to lack of nutrition and fat reserves, and eventually turtles will die from either starvation or desiccation. Potential population level impacts from reduced surface water and drought include lower reproductive rates, reduced recruitment, reduced population growth rate, or changes in distribution.

Decreasing availability of prey is another factor tied to surface water availability and corresponding loss of habitat that may impact the subspecies. We have very limited information on prey availability for the known populations of mud turtles. However, a reduction in surface water will impact the amount of aquatic invertebrate prey available and result in increased competition for prey. Aquatic invertebrates, the primary food source for Sonoyta mud turtles, need surface water and emergent vegetation to survive and complete their life-history functions. Water permanence will affect the diversity of invertebrate prey available for mud turtles, with ephemeral habitats having lower invertebrate diversity than intermittent or perennial habitats (Stanila 2009, p. 38). A reduction in water and emergent vegetation due to ground water pumping will reduce the amount of aquatic invertebrate prey for Sonoyta mud turtles. Adequate prey allows juvenile turtles to grow rapidly before becoming adults and allows adults to have sufficient lipid content to support reproduction. Poor body condition (*i.e.,* low lipids) may be associated with lower clutch size (total number of eggs produced) and, therefore, lower population growth (Rosen and Lowe 1996, pp. 40–43).

There are also native fish at Quitobaquito that may compete with turtles for invertebrate prey. Stomach analysis of turtles at Quitobaquito revealed animals were primarily consuming young shoots of bulrush even though benthic invertebrates were present in the aquatic system. Rosen and Lowe (1996, pp. 32, 41) thought that turtles may not be consuming invertebrates due to competition with native subspecies of desert pupfish (*Cyprinodon macularius eremus*) found at Quitobaquito. Desert pupfish are well known to feed on many of the same invertebrates that Sonoran mud turtles consume (Rosen and Lowe 1996, p. 41). Pupfish densities at Quitobaquito are similar or greater than the density used in an experimental pond study that demonstrated strong effects of desert pupfish on aquatic invertebrate abundance, so that competition between Sonoyta mud turtles and desert pupfish is plausible (Rosen and Lowe, p. 41).

Similarly, like competition with desert pupfish, the establishment of nonnative aquatic vertebrate species may also affect future persistence of the Sonoyta mud turtle. Currently two of the five populations of Sonoyta mud turtles exist with some nonnative species present. Black bullheads and western mosquitofish were introduced to the Rio Sonoyta Papalote reach, and blue tilapia were introduced at Quitovac. These species are now established at these two sites (Rosen *et al.* 2010, pp. 153–154; Minkley *et al.* 2013, p. 289). All of these fish species likely compete with Sonoyta mud turtles for benthic invertebrates or alter the invertebrate community so that benthic invertebrates are reduced. Other nonnative aquatic species including American bullfrogs (*Lithobates catesbeianus*), crayfish (*Orconectes* spp. and *Cherax* spp.), large sunfish (centrarchids), and exotic turtles such as red-eared sliders (*Trachemys scripta elegans*) are not currently present in areas occupied by the Sonoyta mud turtle, but could be released and become established, as they have been in many Sonoran mud turtle populations in the United States (Fernandez and Rosen 1996, pp. 39–41; Hensley *et al.* 2010, pp. 175–176; Drost *et al.* 2011, p. 33).

Bullfrogs, crayfish, large sunfish and catfish (ictalurids) are known to prey upon hatchling and juvenile Sonoran mud turtles. Crayfish, in particular, could decimate a population if introduced (Fernandez and Rosen 1996, pp. 41–43; Hensley *et al.* 2010, pp. 186–187). In addition, crayfish, African cichlid fishes including tilapia, western mosquitofish, and exotic turtles may also disrupt the food chain, which could alter the invertebrate community (Taylor *et al.* 1984, pp. 330–331; Fernandez and Rosen 1996, pp. 39–40; Duncan 2013, p. 1). This, in turn, could decrease type and amount of benthic invertebrate prey available to Sonoyta mud turtles (Fernandez and Rosen 1996, pp. 39–40) (See Section 4.4 and Appendix A of the SSA Report). In addition, turtles isolated in pools as a result of decreased surface water availability may be subject to increased predation from nonnative aquatic predators. Although we cannot specifically quantify effects to Sonoyta mud turtle populations now or in the immediate future we are highly confident that nonnatives are impacting the Papalote and Quitovac populations as described above. In addition, it is possible that in the near future the remaining three populations could become infested with the nonnative species listed above.

In summary, ground water withdrawal and changes to wastewater infrastructure are highly likely to continue into the immediate future and to negatively affect base flow that supports three populations of the Sonoyta mud turtle basin. There is also the potential that Quitovac may be impacted by ground water losses in the future, although we are highly uncertain of this outcome. The sewage lagoon and new wastewater treatment plant are not likely to be impacted by ground water pumping, and may actually contribute to ground water recharge of the Rio Sonoyta. Ongoing and future drought periods are likely to continue and will affect the availability of water in both the United States and Mexico (See Section 4.1 and Appendix A of the SSA Report). In addition, drought is likely to be exacerbated by future climate change, decreasing water availability and increasing evapotranspiration losses.

Effects from climate change are expected to impact all but one population of Sonoyta mud turtles (the sewage lagoon). Although we cannot specifically quantify effects to available surface water, we are highly confident that there will be a reduction in surface water due to ground water pumping and changes to wastewater infrastructure in addition to impacts from climate change. This reduction in surface water reduces or in some populations could eliminate habitat Sonoyta mud turtles need to survive desiccation or complete life-history functions as described above. Our assessment of water reduction in the SSA Report indicates that water loss is an immediate and high-magnitude threat to the species. Quitovac is likely to undergo partial dredging again (and possibly complete dredging), and nonnatives are likely to be introduced again. Nonnatives are still present in the Papalote reach, and it is likely, based on the spread of nonnatives, that all sites could receive nonnative species in the immediate future.

Management actions undertaken by the National Park Service and Quitobaquito Rio Sonoyta Working Group have ameliorated many of the risks to the single Sonoyta mud turtle population in the United States at Organ Pipe Cactus National Monument, and, as explained below, these actions are expected to continue. The Quitobaquito Rio Sonoyta Working Group consists of biologists and managers from the National Park Service (NPS), Arizona Game and Fish Department, FWS, University of Arizona, Arizona Sonora Desert Museum, the National Commission of Natural Protected Areas in Mexico, and private citizens interested in conservation of aquatic native species in the Rio Sonoyta basin of Arizona and Sonora. Organ Pipe Cactus National Monument has already implemented numerous conservation measures recommended for the Sonoyta mud turtle by the Quitobaquito Rio Sonoyta Working Group. Since the 1970's the NPS has implemented conservation measures including trucking water, spring renovation, strengthening the dike that keeps water in the pond, re-lining parts of the pond, and removing bulrush, that have benefited the Quitobaquito population. Efforts by Organ Pipe Cactus National Monument eventually resulted in water levels in the pond stabilizing near historical norms.

One risk that cannot be addressed at Organ Pipe Cactus National Monument is diminishing spring flow that supplies water to Quitobaquito Pond, as the cause is still unknown. (See Section 4.5

of the SSA Report). Per the National Park Service Organic Act (16 U.S.C. 1–4), the Organ Pipe Cactus National Monument will survey for, protect, and strive to recover all species native to national park system units. Based on their past conservation efforts at Quitobaquito, the NPS will continue conservation efforts to maintain water at Quitobaquito pond, to the extent within their power, as they have done since the 1950s and protect the Sonoyta mud turtle as they have since the late 1980s as this is a native species. Further, the endangered desert pupfish and designated critical habitat co-occurs with the Sonoyta mud turtle within the Quitobaquito pond. Some conservation actions to protect the desert pupfish and critical habitat will also protect the Sonoyta mud turtle and its aquatic habitat, as well as some of the riparian habitat surrounding Quitobaquito Springs.

Quitobaquito Rio Sonoyta Working Group management actions in Mexico have included defining the ecological status and distribution of the Sonoyta mud turtle in Sonora, creating new habitat to replace lost habitat, removing nonnative aquatic species, and outreach. Primary actions included nonnative removal and fencing to prevent livestock. However, the fencing has been removed and nonnatives have been reintroduced by the locals. These management actions have not addressed most of the risks to the four populations of the Sonoyta mud turtle in Mexico (See Section 4.5, Management Actions, of the SSA Report). The Quitobaquito and Rio Sonoyta Working Group has been developing a conservation assessment and conservation agreement for five aquatic species for a number of years. This agreement is meant to promote the conservation of a number of species dependent on the aquatic and riparian habitats of the Rio Sonoyta watershed. The agreement would take the form of a Candidate Conservation Agreement. The Sonoyta mud turtle is a species listed in the conservation agreement; it would benefit from the conservation actions proposed. It is unclear when this agreement will be finalized.

In the SSA, we described the viability of the species in a way that characterizes the needs of the species in terms of resiliency, redundancy, and representation. Resiliency is having sufficiently large populations for the species to withstand stochastic events. Stochastic events are those events arising from random factors such as fluctuations in water levels, habitat modification, or introduction of nonnative predators. Redundancy is having a sufficient number of populations for the species to withstand catastrophic events. A catastrophic event is a rare destructive event or episode involving one or more populations and occurring suddenly. Representation is having the breadth of genetic and ecological diversity for the species to adapt to changing environmental conditions. In the SSA Report, populations of the Sonoyta mud turtle having a low level of resiliency are not considered to contribute to the redundancy and representation of the subspecies due to low probability that the populations will persist.

Currently, we consider the Quitobaquito and Sonoyta sewage lagoon populations of the Sonoyta mud turtle to have high resiliency, the Papalote reach population to have moderate resiliency, and the Xochimilco reach and Quitovac populations to have low resiliency. The Quitobaquito population occurs in an area of relatively good habitat and exhibits high survivorship among all age classes with increasing recruitment of juveniles. Resiliency of the four populations in Mexico is less certain as habitat has been greatly reduced in the Papalote and Xochimilco reaches, survivorship among age classes is unknown at the Sonoyta sewage lagoon due to lack of any surveys, and survivorship among age classes is unknown at Quitovac due to recent dredging of all of the aquatic habitat available for mud turtles. Current abundance of mud turtle populations in Mexico is unknown, and we have low confidence that numbers have remained stable.

The viability of the Sonoyta mud turtle depends on maintaining multiple resilient populations over time. The resiliency of Sonoyta mud turtle populations depends on surface water availability, amount of riparian habitat and benthic invertebrates, and absence of nonnative competitors and predators. We expect the five extant Sonoyta mud turtle populations to experience changes to all of these aspects of their habitat, although it may be in different ways under the different conditions. Given our uncertainty regarding when habitats of the Sonoyta mud turtle will experience a reduction or elimination of surface water and corresponding loss of riparian habitat in the future, we forecasted future conditions of the Sonoyta mud turtle under three future plausible scenarios over three time periods (Chapter 5 of the SSA Report). These scenarios focus on surface water availability because this is the driving factor for the other variables impacting Sonoyta mud turtle populations—riparian habitat and prey. For example, if there is a somewhat reduced amount of surface water there would be a reduced amount or reduced quality of riparian area and prey. These factors in turn impact reproduction and recruitment, which drive the population growth. The three scenarios were:

(1) Best Case—All habitats occupied by Sonoyta mud turtle experience no measurable drop in surface water and nonnatives are absent.

(2) Moderate Case—Surface water in habitats occupied by Sonoyta mud turtle is somewhat reduced but not eliminated, and nonnatives remain at status quo.

(3) Worst Case—All surface water at sites occupied by Sonoyta mud turtle is extremely reduced or eliminated, and nonnatives are present in all populations.

We selected three useful timeframes for our forecasting: 7 years, 35 years, and 70 years. We chose 7 years based on the area's drought cycle, 35 years because it incorporates both the maximum lifespan of the species and the mid-century climate projections for the southwestern United States, and 70 years because it is within the range of the available drought and climate change model forecasts and is about twice the maximum lifespan of the species (Lenart 2008, entire; Stritthold *et al.* 2012, entire; Garfin *et al.* 2013, entire; P. Holms, 2016, pers. comm.). Within these timeframes, we considered the three different scenarios that spanned a range of potential conditions that we believe are important influences on the status of the species, and our results describe this range of possible conditions in terms of our projections of how many and where Sonoyta mud turtle populations will persist into the near term.

We assessed the moderate-case scenario as the most likely to occur because this scenario is based on the threats identified above continuing at their current intensity and scale through the various time steps. This scenario projected the current level of stressors associated with the status quo conditions. The moderate-case scenario was the most likely to occur, as explained in the SSA. While full analyses of all scenarios are available in the SSA report, we are only presenting the full results of the moderate-case scenario here because it gives the most realistic projection of the future condition of the subspecies. The worst-case scenario was not found to be very likely because, as explained in the SSA, it is unlikely that all populations will lose all or most of their surface water. Conversely, the best-case scenario of improving conditions was found not to be very likely to occur because this scenario projected no reduction in surface water, which is an unlikely and unrealistic scenario given current climate change projections. Please refer to the SSA report (Service 2016, Chapter 5) for the full analysis of future scenarios.

Under the moderate-case scenario within the 7-year timeframe, we expect the Sonoyta mud turtle's viability to be characterized by lower levels of resiliency, representation, and redundancy than it has currently, which is already reduced as described above. We expect populations at Xochimilco reach and Quitovac to have low population resiliency. In addition, we expect the Sonoyta sewage lagoon to have low population resiliency and its possible extirpation within 7 years. This possible outcome is dependent on exactly when the new wastewater treatment plant begins operating, which will replace the Sonoyta sewage lagoon. The new population at the new wastewater treatment plant will be stocked with animals from the Sonoyta sewage lagoon population. However, aquatic habitat at the new wastewater treatment plant is smaller than the sewage lagoon, and riparian habitat will essentially be nonexistent at first, so the population resiliency at the wastewater treatment plant is expected to be only moderate at the 7-year time step, whereas, the Sonoyta sewage lagoon currently has high population resiliency.

We anticipate the population at Quitobaquito will be highly resilient and the Papalote reach will be moderately resilient at this time step. We expect the three populations with low resiliency, Sonoyta sewage lagoon, Xochimilco reach, and Quitovac, will have only some or few individuals that can complete life functions and breed successfully, and the populations are decreasing and not able to withstand stochastic events. Further, it is possible that one of the low-resiliency populations, Sonoyta sewage lagoon, will be extirpated by this time. Two of the three remaining populations are projected to be moderately resilient and will occur in highly managed habitats—the Quitobaquito population with a spring-fed pond and the wastewater treatment plant that is maintained by wastewater effluent. The Santo Domingo population is considered extirpated. We expect representation and redundancy will also be substantially reduced due to the three populations of low resiliency being functionally extirpated. This leaves three populations with only one being highly resilient and two being moderately resilient, including the wastewater treatment plant, which will be reduced in size from the sewage lagoon it is replacing.

TABLE 2—RIO SONOYTA MUD TURTLE CURRENT AND NEAR-FUTURE POPULATION CONDITION

Country	Population name	Current condition	Moderate-case scenario
			7-year time step
United States	Quitobaquito	High	High.
Mexico	Papalote Reach (Agua Dulce)	Moderate	Moderate.
	Sonoyta Sewage Lagoon	High	Low.
	New Sonoyta wastewater treatment plant	0	Moderate.
	Xochimilco Reach (Sonoyta Reach)	Low	Low.
	Quitovac	Low	Low.
	Santo Domingo	0	0.

Determination

Section 4 of the Act, and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(b)(1)(a), the Secretary is to make endangered or threatened determinations required by section 4(a)(1) solely on the basis of the best scientific and commercial data available to her after conducting a review of the status of the species and after taking into account conservation efforts by States or foreign nations. The standards for determining whether a species is endangered or threatened are provided in section 3 of the Act. An endangered species is any species that is "in danger of extinction throughout all or a significant portion of its range." A threatened species is any species that is "likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range." Per section 4(a)(1) of the Act, in reviewing the status of the species to determine if it meets the definition of endangered or of threatened, we determine whether any species is an endangered species or a threatened species because of any of the following five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination.

The fundamental question before the Service is whether the subspecies warrants protection as an endangered or threatened species under the Act. To make this determination, we evaluated extinction risk, described in terms of the current condition of populations and their distribution (taking into account the risk factors (*i.e.,* threats, stressors) and their effects on those populations). For any species, as population conditions decline and distribution shrinks, the species' overall viability declines and extinction risk increases.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Sonoyta mud turtle. Currently, there are five extant populations, and all are significantly isolated from one another such that recolonization of areas previously extirpated or areas that may be extirpated is extremely unlikely. Expert input provided during the development of the SSA Report indicated that, under the current situation for the five currently occupied sites, connectivity or movement among the populations is a rare occurrence. The species' range has been reduced by 80 to 92 percent in the Rio Sonoyta (Factor A) in Mexico, and current distribution is limited to five populations in three ponds totaling <7 ha (<15.5 ac) and two perennial sections of the Rio Sonoyta totaling 1.5 to 5.5 km (0.9 to 3.4 mi). Two historical populations are extirpated due to loss of perennial water. There are two newly discovered extant populations in addition to the three historical populations that remain. Only three of these populations are of sufficient resiliency to withstand stochastic events.

Habitat loss from anthropogenic ground water withdrawals and long-term drought is occurring rangewide and is likely to continue and increase in the near term (Factor A; Factor E). This reduction in water restricts the limited available habitat and decreases the resiliency of the Sonoyta mud turtle within those habitats. We find that ongoing drought is likely to continue and be exacerbated by climate change, decreasing water availability and increasing evapotranspiration losses (Factor A). This threat is ongoing, rangewide, and expected to increase in the future. Predation by nonnative aquatic species has occurred at two sites in Mexico, although there is uncertainty with regard to the population effects (Factor C). Predation by nonnative aquatic species has been shown to reduce recruitment and population size of other populations of Sonora mud turtle and it is likely to occur in Sonoyta mud turtle populations in the future. The Quitovac population's current habitat was just recently completely dredged, and the status of Sonoyta mud turtles is unknown. Partial dredging in the near term is likely based on past dredging activity. It is reasonably likely that a catastrophic event could occur anytime within the initial 7-year time step analyzed in the SSA Report and that current population resiliency and redundancy are inadequate to maintain population viability.

The implementation of the conservation measures by the National Park Service and the Quitobaquito Rio Sonoyta Working Group has resulted in maintaining the only Sonoyta mud turtle population in the United States and reduces the risk of loss of at least one population in Mexico. However, the conservation measures do not alleviate the threats that are influencing the resiliency, redundancy, and representation of the Sonoyta mud turtle across its range (as described above).

The Act defines an endangered species as any species that is "in danger of extinction throughout all or a significant portion of its range" and a threatened species as any species "that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future." Based on the information presented in the SSA Report for the Sonoyta mud turtle, and the discussion above, we find that the best available scientific and commercial information indicates that the Sonoyta mud turtle is presently in danger of extinction throughout its entire range based on the severity and immediacy of threats currently impacting the species. The overall range has been significantly reduced; the limited remaining habitat and populations are currently threatened by an increase in ground water pumping, which results in reduced spring flows and, therefore, reduced surface water. Reduced surface water results in reduced aquatic habitat for the subspecies where they spend the majority of their time and is needed to avoid desiccation. Further, the reduction in surface water impacts aquatic vegetation used by the Sonoyta mud turtle for cover and by their prey species. Lastly, the reduction in ground water reduces the soil moisture of the riparian area resulting in habitat that is too dry for Sonoyta mud turtles to use for estivation and nesting.

These factors acting in combination reduce the overall viability of the species. The risk of extinction is high because the five remaining populations are small, isolated, and have limited, if any, potential for recolonization. The estimated current and near-term future conditions of the known Sonoyta mud turtle populations as described in the SSA Report lead us to find that the condition and distribution of populations do not provide sufficient resiliency, redundancy, and representation for this subspecies; therefore, we find that the subspecies meets the definition of an endangered species under the Act. Accordingly, on the basis of the best available scientific and commercial information, we propose listing the Sonoyta mud turtle as endangered in accordance with sections 3(6) and 4(a)(1) of the Act.

Under the Act and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. Because we have determined that the Sonoyta mud turtle is endangered throughout all of its range, no portion of its range can be "significant" for purposes of the definitions of "endangered species" and "threatened species." See the Final Policy on Interpretation of the Phrase "Significant Portion of Its Range" in the Endangered Species Act's Definitions of "Endangered Species" and "Threatened Species" (79 FR 37577, July 1, 2014).

We find that a threatened species status is not appropriate for the Sonoyta mud turtle because of the existing contracted range (loss of 80–92 percent of its historic range in Mexico) compared to the historical range, the primary threats are occurring rangewide and are not localized, and the threats are impacting the species now and are ongoing. We find the Sonoyta mud turtle to be in danger of extinction now.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for downlisting or delisting, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our Web site (*http://www.fws.gov/endangered*), or from our Arizona Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.*, restoration of water availability and associated native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands, and, in the case of the Sonoyta mud turtle, cooperation with our counterparts in Mexico. If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of Arizona would be eligible for Federal funds to implement management actions that promote the protection or recovery of the Sonoyta mud turtle. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the Sonoyta mud turtle is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the National Park Service (Organ Pipe Cactus National Monument); issuance of section 404 Clean Water Act permits by the Army Corps of Engineers; and construction and maintenance of roads or highways by the U.S. Customs and Border Protection of the Department of Homeland Security.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered wildlife. The prohibitions of section 9(a)(1) of the Act, codified at 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) endangered wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any listed species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22. With regard to endangered wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. At this time, we are unable to identify specific activities that would not be considered to result in a violation of section 9 of the Act because the Sonoyta mud turtle sites where the species currently occurs are subject to a variety of potential activities, and it is likely that site-specific conservation measures may be needed for activities that may directly or indirectly affect the species. Additionally, most activities subject to consultation include direct effects to the species and/or the aquatic and riparian habitats to which it is inextricably tied. It is difficult to predict an activity already subject to consultation that would not result in anticipated take of individual Sonoyta mud turtles.

Based on the best available information, the following activities may potentially result in a violation of section 9 of the Act; this list is not comprehensive:

(1) Unauthorized handling or collecting of the species.

(2) Destruction/alteration of the species' habitat by discharge of fill material, draining, ditching, tiling, pond construction, stream channelization or diversion, removal or destruction of emergent aquatic vegetation; or diversion or alteration of surface or ground water flow into or out of the wetland (*i.e.*, due to roads, impoundments, discharge pipes, stormwater detention basins, etc.) or in any body of water in which the Sonoyta mud turtle is known to occur.

(3) Direct or indirect destruction of riparian habitat.

(4) Introduction of nonnative species that compete with or prey upon the Sonoyta mud turtle, such as the introduction of nonnative fish and crayfish species.

(5) Release of biological control agents that attack any life stage of this species.

(6) Discharge of chemicals or fill material into any waters in which the Sonoyta mud turtle is known to occur.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Arizona Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

Based on cultural claims maps and reservation boundaries we have on file, the distribution of the Sonoyta mud turtle overlaps areas that may be of interest to the following tribes: Tohono O'odham Nation, Quechan Tribe, Hopi Tribe, Colorado River Indian Tribes, and Cocopah Indian Tribe. On November 20, 2015, we notified these tribes via letter of our intent to conduct a status assessment for the purpose of determining whether the subspecies warrants protection under the Act. In our letter we offered to meet with the tribe to discuss the process, potential impacts to the tribes, and how tribal information may be used in our assessment. In addition, we requested any information they have regarding the subspecies. To date we have not received a response from these any of these tribes. Upon publication of this proposed rule we will send notification letters to these tribes and again extend an invitation to meet and discuss.

References Cited

A complete list of references cited in this rulemaking is available in the SSA Report (U.S. Fish and Fish and Wildlife Service. 2016. Species status assessment report for the Sonoyta mud turtle (*Kinosternon sonoriense longifemorale*), Version 1.0. Albuquerque, NM) that is available on the Internet at *http://www.regulations.gov* at Docket Number FWS–R2–ES–2016–0103, at *https://www.fws.gov/southwest/es/arizona/*, and upon request from the Arizona Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Arizona Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245; unless otherwise noted.

■ 2. In § 17.11(h), add an entry for "Turtle, Sonoyta mud" to the List of Endangered and Threatened Wildlife in alphabetical order under REPTILES to read as set forth below:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
* * * * * * *				
REPTILES				
* * * * * * *				
Turtle, Sonoyta mud	*Kinosternon sonoriense longifemorale.*	Wherever found	E	[**Federal Register** *citation when published as a final rule.*]
* * * * * * *				

Dated: September 7, 2016.

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2016–22754 Filed 9–20–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[4500090022]

Endangered and Threatened Wildlife and Plants; 12-Month Findings on Petitions To List Nine Species as Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12-month petition findings.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce 12-month findings on petitions to list nine species as endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). After a review of the best available scientific and commercial information, we find that listing the angular dwarf crayfish, Guadalupe murrelet, Huachuca springsnail, two Kentucky cave beetles (Clifton Cave and Icebox Cave beetles), *Artemisia campestris* var. *wormskioldii* (northern wormwood), Scripps's murrelet, Virgin Islands coquí, and Washington ground squirrel is not warranted at this time. However, we ask the public to submit to us at any time any new information that becomes available concerning the stressors to any of the nine species listed above or their habitats.

DATES: The findings announced in this document were made on September 21, 2016.

ADDRESSES: These findings are available on the Internet at *http://www.regulations.gov* at the following docket numbers:

Species	Docket No.
Angular dwarf crayfish	FWS–R4–ES–2011–0049
Guadalupe murrelet	FWS–R8–ES–2016–0081
Huachuca springsnail	FWS–R2–ES–2016–0082
Kentucky cave beetles (Clifton Cave and Icebox Cave beetles)	FWS–R4–ES–2016–0032
Artemisia campestris var. *wormskioldii* (Northern wormwood)	FWS–R1–ES–2016–0083
Scripps's murrelet	FWS–R8–ES–2016–0084
Virgin Islands coquí	FWS–HQ–ES–2013–0125
Washington ground squirrel	FWS–R1–ES–2016–0085

Supporting information used to prepare these findings is available for public inspection, by appointment, during normal business hours, by contacting the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**. Please submit any new information, materials, comments, or questions concerning these findings to the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

Species	Contact information
Angular dwarf crayfish	Cary Norquist, Field Supervisor, Mississippi Ecological Services Field Office, 601–965–4900.
Guadalupe murrelet	Steve Henry, Field Supervisor, Ventura Fish and Wildlife Office, 805–644–1766.
Huachuca springsnail	Steve Spangle, Field Supervisor, Arizona Ecological Services Field Office, 602–242–0210.
Kentucky cave beetles (Clifton Cave and Icebox Cave beetles).	Lee Andrews, Field Supervisor, Kentucky Ecological Services Field Office, 502–695–0468.
Artemisia campestris var. *wormskioldii* (Northern wormwood).	Brad Thompson, Deputy State Supervisor, Washington Fish and Wildlife Office, 360–753–6046.
Scripps's murrelet	Steve Henry, Field Supervisor, Ventura Fish and Wildlife Office, 805–644–1766.
Virgin Islands coquí	Janine Van Norman, Chief, Branch of Foreign Species, Headquarters Ecological Services Office, 703–358–2171.
Washington ground squirrel	Paul Henson, Field Supervisor, Oregon Fish and Wildlife Office, 503–231–6179; Eric Rickerson, Field Supervisor, Washington Fish and Wildlife Office, 360–753–9440.

If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Act (16 U.S.C. 1533) requires that, within 12 months after receiving any petition to revise the Federal Lists of Endangered and Threatened Wildlife and Plants that contains substantial scientific or commercial information indicating that listing an animal or plant species may be warranted, we make a finding ("12-month finding"). In this finding, we determine whether listing the angular dwarf crayfish, Guadalupe murrelet, Huachuca springsnail, two Kentucky cave beetles (Clifton Cave and Icebox Cave beetles), *Artemisia campestris* var. *wormskioldii* (northern wormwood), Scripps's murrelet, Virgin Islands coquí, and Washington ground squirrel is: (1) Not warranted; (2) warranted; or (3) warranted, but the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are endangered or threatened species, and expeditious progress is being made to add or remove qualified species from the Federal Lists of Endangered and Threatened Wildlife and Plants (warranted but precluded). Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. We must publish these 12-month findings in the **Federal Register**.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations in part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. The Act defines "endangered species" as any species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and "threatened species" as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, a species may be determined to be an endangered or a threatened species based on any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

We summarize below the information on which we based our evaluation of the five factors provided in section 4(a)(1) of the Act to determine whether the angular dwarf crayfish, Guadalupe murrelet, Huachuca springsnail, two Kentucky cave beetles (Clifton Cave and Icebox Cave beetles), *Artemisia campestris* var. *wormskioldii*, Scripps's murrelet, Virgin Islands coquí, and Washington ground squirrel meet the definition of an endangered or threatened species. More detailed information about these species is presented in the species-specific assessment forms found on *http://www.regulations.gov* under the appropriate docket number (see **ADDRESSES**, above).

In considering what stressors under the five factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat. In that case, we determine if that stressor rises to the level of a threat, meaning that it may drive or contribute to the risk of extinction of the species such that the species warrants listing as an endangered or threatened species as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely affected could suffice. The mere identification of stressors that could affect a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these stressors are operative threats to the species and its habitat, either singly or in combination, to the point that the species meets the definition of an endangered or a threatened species under the Act.

In making our 12-month findings, we considered and evaluated the best available scientific and commercial information regarding the past, present, and future stressors and threats. We reviewed the petition, information available in our files, other available published and unpublished information. This evaluation may include information from recognized experts, Federal, State, tribal, academic, foreign governments, private entities, and the public.

Angular Dwarf Crayfish (*Cambarellus (Pandicambarus) lesliei*)

Previous Federal Actions

On April 20, 2010, we received a petition dated April 20, 2010, from the Center for Biological Diversity, The Alabama Rivers Alliance, The Clinch Coalition, Dogwood Alliance, The Gulf Restoration Network, Tennessee Forests Council, and The West Virginia Highlands Conservancy requesting that we list 404 species, including the angular dwarf crayfish (*Cambarellus (Pandicambarus) lesliei*) as an endangered or threatened species under the Act and designate critical habitat for the species. The petition included supporting information regarding the species' taxonomy and ecology, historical and current distribution, present status, and potential causes of decline. On September 27, 2011 (76 FR 59836), we published a partial 90-day finding on the petition. In that document, we announced our finding that the petition presented substantial scientific or commercial information indicating that listing the angular dwarf crayfish may be warranted, and we initiated a status review for the species.

Background

The angular dwarf crayfish is one of the smallest crayfish in the northern hemisphere, with adults usually less than 25 millimeters (mm) (1.0 inches (in)) long. The species was described from a slow-moving stream "0.5 mi S of Alabama Port, Mobile County, Alabama" by J. F. Fitzpatrick, Jr. and B. A. Laning in 1976. The angular dwarf crayfish is considered a valid species and meets the Act's definition of a species.

This species has been collected from heavily vegetated ponds, slow-moving streams, and backwater areas, and the principal habitat feature appears to be the presence of dense, submerged aquatic vegetation. Little is known about the life history of the angular dwarf crayfish. Fitzpatrick and Laning (1976) observed egg-bearing females in February, April, and June, and females-with-young in both April and June, and they concluded that the species was a year-round breeder. However, they also believed that females did not produce eggs annually. Form I males have been found in February, April, June, August, October, and November.

There is no information on the historical distribution of the angular dwarf crayfish. The known range of the species has expanded with limited collection efforts since the species was described in 1976 using specimens collected in Alabama. It is currently known from 4 localities within, or relatively close to, the Pascagoula River in George County, Mississippi, and 27 localities in the lower Alabama and lower Tombigbee River systems, the Mobile-Tensaw Delta, and Mobile Bay tributaries in Baldwin, Mobile, and Washington Counties, Alabama. The population in Mississippi appears to be disjunct from the Alabama population, but this is possibly an artifact of inadequate collecting effort. The angular dwarf crayfish is difficult to collect and is likely often overlooked. There are limited population and demographic data available for the angular dwarf crayfish.

Summary of Status Review

Potential stressors for the angular dwarf crayfish were identified in the petition as direct alterations of waterways such as impoundment, diversion, dredging and channelization, and draining of wetlands; and land-use activities such as development, agriculture, logging, and mining. A supporting document entitled "Species Assessment and Listing Priority

Assignment Form" (assessment form) for the angular dwarf crayfish provides a summary of the literature and information regarding distribution, habitat requirements, life history, and stressors, as well as an analysis of the stressors to the species. We were unable to find any direct link between landscape-level stressors and the conservation status of the angular dwarf crayfish. Information acquired during our status review indicated that the angular dwarf crayfish continues to persist throughout its limited historical range, and that its known range has expanded due to recent survey efforts. In addition, the species is difficult to collect and identify, and additional populations are likely to be present within the currently known range.

Our review of the best available scientific and commercial information revealed that the angular dwarf crayfish is poorly understood and additional research is needed to more thoroughly define range, abundance, and population trends. However, during our status review, we did not identify any specific stressors that registered as threats to the species or its habitat throughout its currently known range, or within a significant portion of that range. We found no evidence that the species has experienced curtailment of range or habitat, or is affected by disease or predation, commercial or recreational harvest, the inadequacy of existing regulations, or any other natural or manmade factor.

Finding

Based on our review of the best available scientific and commercial information pertaining to the five factors, we find that the stressors potentially acting on the species and its habitat, either singly or in combination, are not of sufficient imminence, intensity, or magnitude to indicate that the angular dwarf crayfish is in danger of extinction (an endangered species), or likely to become endangered within the foreseeable future (a threatened species), throughout all of its range. Because the distribution of the species is narrow and stressors are similar throughout the entire species' range, we found no concentration of stressors that suggests the angular dwarf crayfish may be in danger of extinction in any portion of its range. This finding is based on the continued presence of the species within its historical range, the expansion of the species' known range with limited survey efforts, and the absence of any direct link between the landscape-level stressors identified in the petition and the conservation status of the angular dwarf crayfish throughout its currently known range, or within a significant portion of that range.

Therefore, we find that listing the angular dwarf crayfish as an endangered or threatened species is not warranted throughout all or a significant portion of its range at this time. This document constitutes the Service's 12-month finding on the April 20, 2010, petition to list the angular dwarf crayfish as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the angular dwarf crayfish's species-specific assessment form and other supporting documents (see **ADDRESSES**, above).

Guadalupe Murrelet (*Synthliboramphus hypoleucus*)

Previous Federal Actions

On April 16, 2002, we received a petition dated April 8, 2002, from the Pacific Seabird Group to list the Xantus's murrelet (*Synthliboramphus hypoleucus*) as a threatened species. In our 2004 annual review of species that are candidates for listing under the Act (also called a candidate notice of review or CNOR) published in the **Federal Register** on May 4, 2004 (69 FR 24876), we added the Xantus's murrelet to our list of candidate species and assigned it a listing priority of 5 (high magnitude of nonimminent threats), and determined that listing the Xantus's murrelet was warranted but precluded by higher priority listing actions. We published subsequent warranted-but-precluded findings in later CNORs (70 FR 24870, May 11, 2005; 71 FR 53756, September 12, 2006; 72 FR 69034, December 6, 2007; 73 FR 75176, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; and 80 FR 80584, December 24, 2015).

Background

At the time of the petition, the Xantus's murrelet (*Synthliboramphus hypoleucus*) was recognized as having two subspecies, *S. h. hypoleucus* and *S. h. scrippsi*. However, information received since the petition suggested the two subspecies should be recognized as distinct species, the Guadalupe murrelet (*S. hypoleucus*) and the Scripps's murrelet (*S. scrippsi*). In 2012, the American Ornithologists Union (AOU) approved the elevation of the two subspecies to full species status. Incorporating this taxonomic change into the petitioner's request, we evaluated the two (newly recognized) species separately.

The Guadalupe murrelet is a small diving seabird, approximately 23–25 centimeters (9–10 inches) in length and weighing 148–187 grams (5–7 ounces). The at-sea distribution of the species occurs up to 600 kilometers (373 miles) off the coast of southern British Columbia, Canada, south to Baja California Sur, Mexico. Guadalupe murrelets are confirmed to nest on Guadalupe Island and on the San Benito Islands (comprised of San Benito Oeste, San Benito Medio, and San Benito Este) off the west coast of Baja California, Mexico. A historical breeding site with limited birds was observed on Santa Barbara Island, California, but is no longer in use.

Summary of Status Review

In our current assessment of the status of the species, we developed a Species Status Assessment report (SSA report) outlining the stressors potentially impacting Guadalupe murrelets and their habitat (Species Report—Scripps's Murrelet (*Synthliboramphus scrippsi*) and Guadalupe Murrelet (*Synthliboramphus hypoleucus*)). We consider the SSA report to be the compilation of the best available scientific and commercial information on the status of the Guadalupe murrelet and its habitat. The stressors we evaluated in the species report include: (1) Native predators; (2) nonnative predators; (3) introduced mammals (sheep, goats, cattle, pigs, rabbits, and hares); (4) guano mining; (5) human disturbance; (6) artificial lighting; (7) fishing activity; (8) prey availability; (9) off-shore natural gas exploration and extraction activities; (10) oil pollution; (11) the effects of climate change; and (12) the effects of small population size.

In our assessment, we acknowledge that the Guadalupe murrelet probably underwent steep declines as a result of predation and habitat destruction in the early to mid-1900s, as evidenced by anecdotal and observed accounts. However, no extirpations or steep declines have been observed within the last 40 years, and population numbers remain stable based on the limited survey information. Residual effects from habitat modification and displacement from potential breeding habitat may still be occurring. However, we anticipate that these residual effects will decrease in the future as vegetation recovers naturally and birds slowly move back into previously used breeding habitat. All nonnative predators have been removed from the San Benito Islands. Cats do still occur on the main Guadalupe Island, but only impact a small population of Guadalupe murrelets as the majority nest on off-shore rocks and islets. Some eradication efforts have been conducted, and fencing has been installed around known seabird nesting areas on Guadalupe Island since 2003. Additional conservation efforts include designation of Guadalupe Island as a Biosphere Reserve in June 2005, by the Government of Mexico. Since 2011, there has been a management plan in place on Guadalupe Island, implementing measures to restrict access, limit existing human activity, and provide measures for restoration and conservation of endemic species and their habitats.

Finding

Based on our review of the best available scientific and commercial information pertaining to the five factors, we find that the stressors impacting the species have either been eliminated or reduced to the point where they are not of sufficient imminence, intensity, or magnitude, either singularly or cumulatively, to indicate that the Guadalupe murrelet is currently in danger of extinction (an endangered species), or likely to become endangered within the foreseeable future (a threatened species) throughout all or a significant portion of its range. This is based on the relatively stable population and distribution of the species and the fact that conservation management is occurring throughout the species' range to minimize impacts to both the habitat and individuals.

In considering any significant portion of the range of this species, we evaluated whether the stressors facing Guadalupe murrelet might be geographically concentrated in any one portion of its range and whether these stressors manifest as threats to Guadalupe murrelet such that it would be presently in danger of extinction throughout all of the species' range. We found no portion of its range where the stressors are significantly concentrated or substantially greater than in any other portion of its range. As a result, we find that factors affecting Guadalupe murrelet are essentially uniform throughout its range, indicating no portion of the range warrants further consideration of possible endangered or threatened status under the Act.

Therefore, we find that listing the Guadalupe murrelet as an endangered or threatened species or maintaining the species as a candidate under the Act is not warranted at this time, and consequently we are removing it from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Guadalupe murrelet, and constitutes the Service's 12-month finding on the April 8, 2002, petition to list the Guadalupe murrelet as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the Guadalupe murrelet's species-specific assessment form, the SSA report, and other supporting documents (see **ADDRESSES**, above).

Scripps's Murrelet (*Synthliboramphus scrippsi*)

Previous Federal Actions

On April 16, 2002, we received a petition dated April 8, 2002, from the Pacific Seabird Group to list the Xantus's murrelet (*Synthliboramphus hypoleucus*) as a threatened species. In our 2004 CNOR, published in the **Federal Register** on May 4, 2004 (69 FR 24876), we added the Xantus's murrelet to our list of candidate species and assigned it a listing priority of 5 (high magnitude of nonimminent threats), and determined that listing the Xantus's murrelet was warranted but precluded by higher priority listing actions. We published subsequent warranted-but-precluded findings in later CNORs (70 FR 24870, May 11, 2005; 71 FR 53756, September 12, 2006; 72 FR 69034, December 6, 2007; 73 FR 75176, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; and 80 FR 80584, December 24, 2015).

Background

At the time of the petition, the Xantus's murrelet (*Synthliboramphus hypoleucus*) was recognized as having two subspecies, *S. h. hypoleucus* and *S. h. scrippsi*. However, information since the petition suggested the two subspecies should be recognized as distinct species, the Guadalupe murrelet (*S. hypoleucus*) and the Scripps's murrelet (*S. scrippsi*). Incorporating this taxonomic change into the petitioner's request, we evaluated the two (newly recognized) species separately.

The Scripps's murrelet is a small diving seabird, approximately 23–25 centimeters (9–10 inches) in length and weighing 148–187 grams (5–7 ounces). The at-sea distribution of the species occurs up to 600 kilometers (373 miles) off the coast of southern British Columbia, Canada, south to Baja California, Mexico. Scripps's murrelets are confirmed to nest on the Channel Islands (San Miguel, Santa Cruz, Anacapa, Santa Barbara, Santa Catalina, and San Clemente Islands) off the California coast and on several islands off the coast of Baja California, Mexico (Coronado, Todos Santos, San Jeronimo, and San Benito Islands). The species is present on the island of San Martin, Mexico, but there is no confirmed breeding.

Summary of Status Review

In our current assessment of the status of the species, we developed a SSA report outlining the stressors potentially impacting Scripps's murrelets and their habitat (Species Report—Scripps's Murrelet (*Synthliboramphus scrippsi*) and Guadalupe Murrelet (*Synthliboramphus hypoleucus*). We consider the SSA report to be the compilation of the best available scientific and commercial information on the status of the Scripps's murrelet and its habitat. The stressors we evaluated in the species report include: (1) Native predators; (2) nonnative predators; (3) introduced mammals (sheep, goats, cattle, pigs, rabbits, and hares); (4) guano mining; (5) human disturbance; (6) artificial lighting; (7) fishing activity; (8) prey availability; (9) off-shore natural gas exploration and extraction activities; (10) oil pollution; (11) the effects of climate change; and (12) the effects of small population size.

In our assessment, we acknowledge that the Scripps's murrelet probably underwent steep declines as a result of predation and habitat destruction in the early to mid-1900s as evidenced by anecdotal and observed accounts; however, no extirpations or steep declines have been observed within the last 40 years and populations numbers remain stable, based on the limited survey information. Population numbers of Scripps's murrelet have rebounded on Santa Barbara Island and Anacapa Island after the removal of nonnative predators and habitat restoration (both natural and prescripted), and now make up over 40 percent of the breeding population for the species. Residual effects from habitat modification and displacement from potential breeding habitat may still be occurring. However, we anticipate that these residual effects will decrease in the future as vegetation recovers naturally and birds slowly move back into previously used breeding habitat. All nonnative predators have been removed from all breeding and nonbreeding islands. Additional conservation efforts include restrictions of human activity near breeding areas on the Channel Islands and designation of several of the islands off the coast of Baja California as natural reserves by the Government of Mexico. These measures restrict access and limit human activity and provide measures for restoration and conservation of endemic species.

Finding

Based on our review of the best available scientific and commercial information pertaining to the five factors, we find that the stressors impacting the species have either been eliminated or reduced to the point where they are not of sufficient imminence, intensity, or magnitude to indicate that the Scripps's murrelet is currently in danger of extinction (endangered), or likely to become endangered within the foreseeable future (threatened) throughout all or a significant portion of its range. This is based on stable or increasing populations and distribution of the species and the fact that conservation management is occurring throughout the species' range for both impacts to habitat and individuals.

In considering any significant portion of the range of this species, we evaluated whether the stressors facing Scripps's murrelet might be geographically concentrated in any one portion of its range and whether these stressors in a portion of its range manifest as threats to Scripps's murrelet such that it would be presently in danger of extinction throughout all of the species' range. We found no portion of its range where the stressors are significantly concentrated or substantially greater than in any other portion of its range. As a result, we find that factors affecting Scripps's murrelet are essentially uniform throughout its range, indicating no portion of the range warrants further consideration of possible endangered or threatened status under the Act.

Therefore, we find that listing the Scripps's murrelet as an endangered or threatened species or maintaining the species as a candidate under the Act is not warranted at this time, and consequently we are removing this species from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Scripps's murrelet, and constitutes the Service's 12-month finding on the 2002 petition to list the Scripps's murrelet as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the Scripps's murrelet's species-specific assessment form, the SSA report, and other supporting documents (see **ADDRESSES**, above).

Huachuca Springsnail (*Pyrgulopsis thompsoni*)

Previous Federal Actions

We designated the Huachuca springsnail as a Category 2 candidate in the Animal Notice of Review published in the **Federal Register** on January 6, 1989 (54 FR 554). Category 2 candidate species were those species for which listing as an endangered species or a threatened species was possibly appropriate, but for which biological information sufficient to support a proposed rule was lacking. The February 28, 1996, CNOR (61 FR 7596) discontinued recognition of categories and in that document we designated the Huachuca springsnail a candidate species as currently defined. On May 11, 2004, we received a petition dated May 4, 2004, from the Center for Biological Diversity, requesting that we list 225 plants and animals, including the Huachuca springsnail, as endangered species under the Act and designate critical habitat. In response to the May 4, 2004, petition to list the Huachuca springsnail as an endangered species, we published a warranted-but-precluded 12-month finding in the **Federal Register** on May 11, 2005 (70 FR 24870). We published subsequent warranted-but-precluded 12-month findings in later CNORs (71 FR 53756, September 12, 2006; 72 FR 69034, December 6, 2007; 73 FR 75176, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; and 80 FR 80584, December 24, 2015).

Background

The Huachuca springsnail is a small (1.7 to 3.2 millimeters (0.07 to 0.13 inches)) aquatic snail (class Gastropoda; subclass Rissooidea; family Hydrobiidae) endemic to Santa Cruz and Cochise Counties in southeastern Arizona and adjacent portions of northern Sonora, Mexico. There are an estimated 29 historical spring ecosystem sites (23 on Federal land, 4 on private land, 2 in Mexico), of which 23 are confirmed as occupied sites. The Huachuca springsnail is most commonly found in rheocrene ecosystems (water emerging from the ground as a flowing stream) where proximity to spring vents plays a key role in their life history. Most information regarding Huachuca springsnail life history is derived from closely related congeners or other members of the Hydrobiidae family. Springsnails are gill-breathing and have an entirely benthic life cycle with a typical lifespan of about one year. Female springsnails are noticeably larger than males and are oviparous (egg-laying), and reproduction occurs throughout the year in warm water and seasonally in colder environments. Springsnails are known to feed primarily on periphyton, which is a complex mixture of algae, detritus, bacteria, and other microbes that live upon submerged surfaces in aquatic environments. Due to their small size, springsnail mobility is limited and significant dispersal events are unlikely to occur. Suitable habitat for springsnails includes spring ecosystems that produce running water with firm substrates characterized by cobble, gravel, woody debris, and aquatic vegetation.

Summary of Status Review

The SSA report for the Huachuca springsnail provides a summary of the information assembled and reviewed by the Service and incorporates the best available scientific and commercial information for this species. In the SSA report, we evaluated the potential stressors that could be affecting Huachuca springsnail populations. Those stressors that could meaningfully impact the status of the species include: (1) Reduction of spring discharge; (2) springhead modification; (3) conversion from lotic (flowing water) to lentic (standing water) systems; (4) aquatic vegetation management; (5) water contamination; (6) predation; and (7) competition. We evaluated each of these factors for their potential to have population- and species-level effects to the Huachuca springsnail (for further information, please refer to the Huachuca springsnail SSA report). Many of these stressors are ameliorated by ongoing conservation efforts. The majority of springs that are occupied by the Huachuca springsnail are on Federal lands where there are some existing protections in place related to general land use plans (Department of Defense and U.S. Forest Service). In addition, a candidate conservation agreement (CCA) is under development that could potentially enhance existing conservation measures and protections.

The Huachuca springsnail continues to occupy a very large portion of its estimated historical range (found in 23 of 29 spring sites surveyed since 2004), and a substantial portion of the spring habitat throughout the species' current range is relatively intact (25 of 29 sites assessed as either high- or medium-quality habitat). Current Huachuca springsnail occupancy, and the amount and distribution of high- and medium-quality habitat, supports sufficient resiliency to sustain the Huachuca springsnail into the near future. These levels are commensurate with historical information, and there is no information to suggest that the species will not continue to occur at these levels.

In considering the foreseeable future as it relates to the status of the Huachuca springsnail, we considered the stressors acting on the species and looked to see if reliable predictions about the status of the species in response to those factors could be drawn. We considered whether we could reliably predict any future effects that might affect the status of the species, recognizing that our ability to make reliable predictions into the future is limited by the variable quantity and quality of available data about impacts to the Huachuca springsnail and the species' response to those impacts.

For the Huachuca springsnail, the most significant stressor looking into the future is climate change, resulting in both springhead modification and spring discharge decline. When evaluated under plausible future scenarios, however (see Huachuca springsnail SSA report), the best available scientific and commercial information does not show that these stressors to the Huachuca springsnail are likely to result in meaningful population declines in the foreseeable future.

Finding

Based on our review of the best available scientific and commercial information pertaining to the five listing factors, we find that the stressors acting on the species and its habitat, either singly or in combination, are not of sufficient imminence, intensity, or magnitude to indicate that the Huachuca springsnail is in danger of extinction (an endangered species), or likely to become endangered within the foreseeable future (a threatened species), throughout all of its range. This is based on the relatively stable population and distribution of the species and the fact that conservation management is occurring throughout the species' range to minimize impacts to both the habitat and individuals.

We also evaluated the current range of the Huachuca springsnail to determine if there are any apparent geographic concentrations of potential threats to the species. Generally speaking, the risk factors affecting the Huachuca springsnail occur throughout the range of the species; however, portions of the range that are outside of areas currently afforded protection from future spring modifications (*i.e.,* springs located on private land and in Mexico) may be subject to impacts not found throughout the range of the species, which is mostly located on Federal lands. If we assume that all areas on unprotected land had springhead modification that resulted in the habitat being made entirely unusable to the Huachuca springsnail, that conversion would represent a loss of 21 percent of available habitat. At this scale, we have no information to suggest that the remaining 79 percent of available habitat on Federal lands would not continue to support sufficient Huachuca springsnail resiliency and redundancy. Additionally, there is no genetic information available for the populations on private land and in Mexico to suggest there are unique genetic values for these areas that would need to be maintained to support representation. Based on this analysis, we conclude that the portion of the range of the Huachuca springsnail on Federal lands (79 percent of available habitat) contains sufficient redundancy, resiliency, and representation that ensure that the Huachuca springsnail would not be in danger of extinction in a significant portion of its range if the available habitat on non-Federal lands (21 percent of available habitat) were to become unusable for the species.

Based on the above evaluations, we find that listing the Huachuca springsnail as an endangered or threatened species or maintaining the species as a candidate is not warranted throughout all or a significant portion of its range at this time, and consequently we are removing it from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Huachuca springsnail, and constitutes the Service's 12-month finding on the May 4, 2004, petition to list the Huachuca springsnail as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the Huachuca springsnail's species-specific assessment form, SSA report, and other supporting documents (see **ADDRESSES**, above).

Two Kentucky Cave Beetles (Clifton Cave Beetle (*Pseudanophthalmus caecus*) and Icebox Cave Beetle (*Pseudanophthalmus frigidus*))

Previous Federal Actions

The Icebox Cave beetle was added to the Federal list of candidate species in the 1989 CNOR (54 FR 554; January 6, 1989) as a Category 2 candidate species. The Clifton Cave beetle was added to the Federal list of candidate species in the 1994 CNOR (59 FR 58982; November 15, 1994) as a Category 2 candidate species. When the 1996 CNOR (61 FR 7596) discontinued recognition of categories, the Icebox Cave beetle and Clifton Cave beetle were no longer considered candidate species.

On October 30, 2001, the Service added both the Icebox Cave beetle and the Clifton Cave beetle to the candidate list through the Service's own internal process (66 FR 54808). However, the Service received a petition from the Center for Biological Diversity and others, dated May 11, 2004, to list eight cave beetles, including the Clifton Cave beetle and Icebox Cave beetle. In the May 11, 2005, CNOR (70 FR 24870), the Service determined that listing the Clifton Cave beetle and Icebox Cave beetle was warranted but precluded by higher priority listing decisions. Further, we have included both species addressed in this finding in every CNOR since 2001 (66 FR 54808, October 30, 2001; 67 FR 40657, June 13, 2002; 69 FR 24876, May 4, 2004; 70 FR 24870, May 11, 2005; 71 FR 53756, September 12, 2006; 72 FR 69034, December 6, 2007;

73 FR 75176, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; and 80 FR 80584, December 24, 2015).

Background

The species are small (about 4 millimeters in length), predatory cave beetles that occupy moist habitats containing organic matter transported from sources outside the cave environment. Members of the *Pseudanophthalmus* genus vary in abundance from fairly widespread species that are found in many caves to species that are extremely rare and often restricted to only one or two caves. The two beetles addressed by this finding are examples of the latter group as they are restricted to one or two cave habitats in Kentucky. The Clifton Cave Beetle is known from two caves (Clifton Cave and Richardson's Spring Cave) in Woodford County, while the Icebox Cave beetle is known from one cave (Icebox Cave) in Bell County.

Summary of Status Review

When the Clifton Cave beetle and Icebox Cave beetle were first identified as candidates for protection under the Act (66 FR 54808; October 30, 2001), the Service considered both species to be vulnerable to habitat destruction or modification caused by a disruption of the natural inflow of energy into the cave environment; we considered both species to be vulnerable to habitat disturbance within the cave environment resulting from vandalism, pollution, or sedimentation; and we noted the inadequacy of existing regulatory mechanisms to ameliorate those threats. In the 2005 CNOR (70 FR 24879; May 11, 2005), we also considered the species' restricted distribution and perceived small population sizes to increase their vulnerability to these effects, and we recognized the potential of these characteristics to limit the species' natural exchange of genetic material, leading to lower genetic diversity and reduced fitness. Both species were assigned a listing priority number (LPN) of 5, which reflects threats of a high magnitude that are not considered imminent.

Over the last year, new field surveys and monitoring efforts for the Clifton Cave beetle and Icebox Cave beetle have improved our understanding of the species' distribution and threats. A supporting document entitled "Species Assessment and Listing Priority Assignment Form" (assessment form) for each of the two cave beetle species provides a summary of the literature and information regarding distribution, habitat requirements, life history, and stressors, as well as a detailed analysis of the stressors to the species. Based on these findings, we have re-examined each species' status and re-evaluated the magnitude and imminence of their threats. We acknowledge that the species have narrow ranges and are sometimes difficult to locate within known habitats; however, based on these new field surveys we have determined that each species' overall status is more secure than previously believed.

With respect to the Clifton Cave beetle, we have no evidence suggesting that the closure of Clifton Cave has harmed the species. Closure of the cave likely benefited the species, as the cave did not appear to be accessible to humans prior to its original disturbance in the early 1960s. Land use surrounding Clifton Cave has not changed dramatically since the 1960s, so we do not expect that habitats within the cave have been disturbed, nor do we expect a future rise in any habitat-related stressors. Due to the consistent land use and low disturbance within the watershed, we also expect that energy inputs via sinkholes, rock fissures, or other karst windows have been maintained, and have provided the energy needed to maintain the cave ecosystem.

Agricultural land use is even more prevalent in areas surrounding the species' other known cave, Richardson's Spring Cave; however, recent surveys demonstrate that the Clifton Cave beetle has persisted within the cave for over 20 years and continues to be present at levels similar to (or perhaps higher than) those observed in 1994. The species' persistence and high relative abundance over the past two decades indicate that any potential habitat stressors related to agriculture or small population size have not been sufficient to adversely affect the species. The species' persistence also suggests that physical disturbance and vandalism caused by human entry is not a threat (Service 2016, entire). The cave's low ceiling and narrow passage are not favorable for human visitors, and Lewis and Lewis observed no evidence of recent human entry during surveys in 2015.

With respect to the Icebox Cave beetle, ground disturbance associated with development, agriculture, or resource extraction does not appear to pose a current threat to the species. There is visible evidence of past logging (*e.g.*, abandoned, unpaved roads) near the cave's entrance and some residential development in nearby Pineville, Kentucky, but areas surrounding the cave entrance are forested and remain relatively undisturbed. Land use surrounding the cave has changed little since the beetle's discovery in 1963, and we do not expect this to change. Because of these conditions, we also expect that energy inputs via sinkholes or other karst windows have likely been maintained and will continue to provide energy needed to support the cave ecosystem. Our review of current land use and the species' persistence within Icebox Cave for over 50 years indicates that stressors associated with ground disturbance are not occurring at levels that would cause negative population trends for the Icebox Cave beetle.

Icebox Cave has a long history of human visitation, and the cave has been heavily disturbed as evidenced by extensive graffiti on cave walls and several altered (broken) formations. Despite this disturbance, recent surveys by Lewis and Lewis demonstrate the Icebox Cave beetle continues to occur in Icebox Cave, the species has persisted within the cave for over 50 years, and it continues to be present at levels similar to (or perhaps greater than) those observed previously (1963 and 1979). The species' persistence over the past five decades suggests that the level of physical disturbance and vandalism observed within the cave has not risen to the level that would threaten the species' continued existence or alter its population levels within the cave. There is also recent evidence that human disturbance within Icebox Cave has all but ceased. Lewis and Lewis observed no evidence of recent human visitation or entry, no fresh garbage, and no recent graffiti.

We also have no evidence that small population size represents a threat to the Icebox Cave beetle. Only a total of four individuals have been observed in Icebox Cave since 1963, but recent observations by Lewis and Lewis demonstrate the species continues to occur in Icebox Cave and in numbers similar to those reported by previous investigators. The small number of beetles reported from Icebox Cave is not unusual; other *Pseudanophthalmus* species have been reported in low densities. We believe it is reasonable to assume that some *Pseudanophthalmus* species have always occurred in low but stable numbers and this is a normal aspect of their life history.

Finding

Based on our review of the best available scientific and commercial information pertaining to the five threat factors, we find that the stressors acting on these species and their habitats, either singly or in combination, are not of sufficient imminence, intensity, or magnitude to indicate the Clifton Cave beetle or Icebox Cave beetle are in danger of extinction (an endangered species), or likely to become endangered within the foreseeable future (a threatened species), throughout all of their respective ranges.

We evaluated the current ranges of the Clifton Cave beetle and Icebox Cave beetle to determine if there is any apparent geographic concentration of potential threats for these species. Both species have a relatively small range that is limited to one or two cave systems. We examined potential stressors including human visitation, agricultural activities (livestock grazing, row crops), commercial and residential development, resource extraction (logging), disease, predation, sources of water quality impairment, and small population size. We found no concentration of stressors that suggests that either of these cave beetles may be in danger of extinction in a portion of their respective ranges. Therefore, we find that listing the Clifton Cave beetle and Icebox Cave beetle as an endangered or threatened species under the Act throughout all or a significant portion of their respective ranges is not warranted at this time, and consequently we are removing both species from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Clifton Cave beetle and Icebox Cave beetle, and constitutes the Service's 12-month finding on the May 11, 2004, petition to list the Clifton Cave beetle and Icebox Cave beetle as endangered or threatened species. A detailed discussion of the basis for this finding can be found in the Clifton Cave beetle's and Icebox Cave beetle's species-specific assessment forms and other supporting documents (see **ADDRESSES**, above).

Artemisia Campestris **Var.** ***Wormskioldii*** **(Northern Wormwood)**

Previous Federal Actions

In this and previous Federal actions we refer to northern wormwood as *Artemisia borealis* var. *wormskioldii.* However, northern wormwood is currently recognized by regional botanical authorities as *Artemisia campestris* L. var. *wormskioldii* (Besser) Cronquist.

Artemisia campestris var. *wormskioldii* was first recognized as a Category 2 candidate species in the September 27, 1985, review of plant taxa for listing as endangered or threatened species (50 FR 39526). In the February 21, 1990, CNOR, we changed *A. campestris* var. *wormskioldii* 's candidate status to Category 1, a species for which substantial information on biological vulnerability and threat(s) was available to support proposals for listing as endangered or threatened species, but issuance of the proposed rule was precluded by other higher priority listing actions (55 FR 6184). In the February 28, 1996, CNOR, we discontinued the use of categories and removed *A. campestris* var. *wormskioldii* from candidate status (61 FR 7596).

In the October 25, 1999, CNOR, we added *Artemisia campestris* var. *wormskioldii* back to the candidate list (64 FR 57534). At that time, this species was assigned a listing priority number of 3 (threat facing the subspecies was of high magnitude and imminent) as outlined in our Listing and Recovery Priority Guidelines (48 FR 43098; September 21, 1983). We were petitioned to list this species by the Center for Biological Diversity and others on May 11, 2004. *A. campestris* var. *wormskioldii* retained the same status in our CNORs published since 2001 (66 FR 54808, October 30, 2001; 67 FR 40657, June 13, 2002; 69 FR 24876, May 4, 2004; 70 FR 24870, May 11, 2005; 71 FR 53756, September 12, 2006; 72 FR 69034, December 6, 2007; 73 FR 75176, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; and 80 FR 80584, December 24, 2015).

Background

Artemisia campestris var. *wormskioldii* is a perennial plant in the family Asteraceae (asters or sunflowers). It is generally low-growing, reaching 15 to 30 centimeters (6 to 12 inches) average height, and has a taproot. Historically, northern wormwood was found on exposed basalt, cobbly-sandy terraces, and sandy habitat in riparian areas along the banks of the Columbia River at elevations above mean sea level ranging from 50 to 150 meters (160 to 500 feet).

The available information indicates that *Artemisia campestris* var. *wormskioldii* is a narrow endemic that may always have existed in only a few, small populations at any one time. Currently, *A. campestris* var. *wormskioldii* is known to exist naturally at two sites, Beverly and Miller Island, located respectively in Grant and Klickitat Counties, Washington. Northern wormwood has been planted at five additional locations with the aim of creating new populations within its historical range. Introduction sites in Oregon include Squally Point and Rock Creek Park in Wasco County, and Rufus Island in Sherman County. Introduction sites in Washington include Johnson Island in Benton County and Island 18 in Franklin County. With the exception of Rock Creek Park (owned by the City of Mosier, Oregon), and Squally Point (part of Mayer State Park, Oregon), all of the locations where northern wormwood is found are located on Federal land.

Summary of Status Review

A supporting document entitled "Species Assessment and Listing Priority Assignment Form" (assessment form) provides a summary of the literature and information regarding *Artemisia campestris* var. *wormskioldii*'s distribution, habitat requirements, life history, and stressors, as well as a detailed analysis of the stressors to the species. This evaluation includes information from all sources, including Federal, State, tribal, academic, and private entities and the public. We consider this supporting document the best available scientific and commercial information.

We previously identified potential stressors (natural or human-induced negative pressures affecting individuals or subpopulations of a species) on *Artemisia campestris* var. *wormskioldi,* to include: (1) Altered hydrology; (2) erosion; (3) trampling; (4) nonnative, invasive plants; (5) herbivory; (6) climate change; (7) fire; and (8) genetic and other small-population issues. Dam construction, associated changes in flow and sediment regimes, deep pool formation behind the dams, and related shoreline development (such as roads, railroads, and riprap) likely caused the loss of historical habitat of northern wormwood, and as a result of these changes, little suitable habitat may remain within the plant's documented historical range. The habitat within the known historical range, as well as some other areas of suitable habitat, have been surveyed by knowledgeable biologists for additional populations of *A. campestris* var. *wormskioldii* since 2002, and the likelihood is low that undiscovered populations exist in these areas. The current hydrology in the Columbia River may have some effect on individual *A. campestris* var. *wormskioldii* plants and on their habitat; high flows in some years have caused mortality of recently transplanted individuals) and also have been correlated with large flushes of seedlings. However, the best available scientific and commercial information does not indicate that current flow regimes or past development have current or ongoing population-level effects on the abundance and distribution of *A. campestris* var. *wormskioldii.*

Natural erosion by wind and water of the sandy substrate has been observed at Miller Island and Squally Point and has caused mortality of individual *Artemisia campestris* var. *wormskioldii* plants and decreased seedling survival. Deposition of sand has buried plants on Miller Island, and an inverse relationship evidently exists between sand deposition and the number of *A. campestris* var. *wormskioldii* plants on the island in a given year. Since 2010, the number of mature plants has increased annually on Miller Island, and percent sand cover in *A. campestris* var. *wormskioldii* monitoring plots varied and decreased overall over the same period. This phenomenon has not been observed at the Beverly site or the other introduced sites.

In the past, both natural populations of *Artemisia campestris* var. *wormskioldii* suffered from trampling by people (Beverly and Miller Island) and trampling and herbivory by grazing cattle (Miller Island only). People using these sites for recreation inadvertently trampled plants, and on Miller Island, cattle reportedly uprooted individual plants growing in loose, sandy substrate and may also have acted as a vector for nonnative plant species. However, grazing was eliminated from Miller Island in 1988, and cattle are not present there today or at any other site occupied by *A. campestris* var. *wormskioldii.* Foot traffic and boat launching were curtailed at Beverly with the construction of a fence to protect the *A. campestris* var. *wormskioldii* population. Trampling by people and cattle and herbivory by cattle, therefore, are unlikely to be population-level stressors to *A. campestris* var. *wormskioldii* today or in the foreseeable future. The extent of herbivory by native animals is largely unknown, but based on available information, it is likely to be minor and have no population-level impacts on *A. campestris* var. *wormskioldii.*

Nonnative, invasive plants occur at most of the sites where *Artemisia campestris* var. *wormskioldii* occurs. Dalmatian toadflax (*Linaria dalmatica*) and diffuse knapweed (*Centaurea diffusa*) are present in the *A. campestris* var. *wormskioldii* population at Beverly, where monitoring and regular treatment keep them under control. At Miller Island, diffuse knapweed and cheatgrass (*Bromus tectorum*) are present but in low density. Among the sites where *A. campestris* var. *wormskioldii* has been introduced, indigo bush (*Amorpha fruticosa*) occurs on Rufus Island, and indigo bush, diffuse knapweed, and rush skeletonweed (*Chondrilla juncea*) plants occur at Squally Point. Although initial treatment of nonnative plants occurred at both of these sites, follow up treatments have not yet occurred. Without regular intervention, these nonnative plants can spread into new areas, including into patches of *A. campestris* var. *wormskioldii,* and they are likely to compete with *A. campestris* var. *wormskioldii* for resources. Although the impacts of nonnative, invasive plant species on ecosystems generally are well known, there is no prior documentation or current, direct evidence of a negative response in *A. campestris* var. *wormskioldii* to the presence of nonnative, invasive plant species. Thus, we can only speculate about potential effects on *A. campestris* var. *wormskioldii* and about the imminence and severity of those effects if they occur. The species of nonnative, invasive plants and efforts to control them (current and anticipated) are not uniformly distributed across the sites where *A. campestris* var. *wormskioldii* occurs. Therefore, if invasive plants have negative impacts to *A. campestris* var. *wormskioldii,* those potential impacts, and whether and when they might be expressed, are likely to be different at different sites. We do anticipate, however, that ongoing treatment of nonnative, invasive plants will occur as needed at *A. campestris* var. *wormskioldii* sites, especially given the current investment in establishing new populations of *A. campestris* var. *wormskioldii* and the long-term, ongoing interest and involvement of our State and other partners in the conservation of this rare plant.

With only two known naturally occurring populations and two of five introduction sites with documented natural recruitment, *A. campestris* var. *wormskioldii* has a limited capacity to withstand stochastic events such as harsh winter conditions, prolonged droughts, and fire. For example, a steep decline in the number of adult *A. campestris* var. *wormskioldii* plants at the Beverly site in 2009 may have been caused in part by the previous winter having been unusually cold and long. However, whether the harsher than average winter was related to climate change is not known.

Climate model projections for the Pacific Northwest Region indicate a continued increase in temperature, with changes in annual mean maximum temperature projected to be largest in the summer months). Precipitation in this region is projected to remain close to current levels, but mean runoff is expected to peak earlier in the year. The projected effects of climate change in the Pacific Northwest, including effects on water management in the Columbia River basin, may exacerbate the effects of drought, invasive species, and fire on *Artemisia campestris* var. *wormskioldii* and its habitat. Although *A. campestris* var. *wormskioldii* populations may experience reduced reproduction and increased mortality as a result of climate fluctuations today and the effects of climate change in the future, the available information does not point to current impacts of these stressors on the species or allow us to reasonably predict the imminence or severity of the cumulative effects of climate change on *A. campestris* var. *wormskioldii* or its habitat.

To date, fire has not been a limiting factor for *Artemisia campestris* var. *wormskioldii* at Beverly or Miller Island. Because bio-fuel accumulation (from native and nonnative plants) is generally low in the sand, gravel, and cobble bars where this species occurs, fire has not influenced the status of northern wormwood individuals or populations. Although *A. campestris* var. *wormskioldii* may be top-killed by fire, the likelihood of an entire population succumbing to or being able to recover from a fire is unknown). Related subspecies have been shown to persist on repeatedly burned sites.

The two naturally occurring populations of *Artemisia campestris* var. *wormskioldii* are separated by a large distance, more than 200 miles (320 kilometers), likely negating the possibility of gene exchange. Loss of genetic variability can affect disease resistance, adaptive capacity, and reproductively compatible gene combinations (genotypes) in the affected species. Small populations are more susceptible to inbreeding, which can reduce the fitness of offspring. However, the historical rate of genetic exchange among *A. campestris* var. *wormskioldii* populations is unknown, and the best available scientific and commercial information does not indicate that *A. campestris* var. *wormskioldii* has lost, or is losing, genetic variability or experiencing inbreeding depression as a result. In addition, plantings to augment natural populations and establish new populations were begun in 2006 and are ongoing.

To date, *Artemisia campestris* var. *wormskioldii* has been introduced to five sites within the historical range to expand the number of populations, increase distribution and abundance, decrease isolation, and buffer potential risks faced by small populations. Seeds collected from the two natural populations were used to propagate plants for these introductions, and plantings have been done experimentally to determine microsite conditions where plants are most likely to survive and become established. Modest natural recruitment has been documented at the two oldest sites, initially planted in 2008 and 2011. We anticipate that the genetic diversity in the two natural populations of *A. campestris* var. *wormskioldii* will continue to be represented at existing and future introduction sites.

Regulatory mechanisms, such as designation by Bureau of Land Management and U.S. Forest Service as a sensitive species through the Interagency Special Status/Sensitive Species Program, the species conservation plan under the Federal Energy Regulatory Commission licensing agreement for the Priest Rapids Hydroelectric Project, and current State-level protections in Oregon and Washington, have resulted in some increased protection of the natural populations of *Artemisia campestris* var. *wormskioldii,* some control of invasive plant species in some sites where *A. campestris* var. *wormskioldii* occurs, and amelioration of stressors such as trampling by livestock and by people (*e.g.,* at the Beverly and Miller Island sites). Conservation measures undertaken for the species have shown variable results at the five introduction sites, including two nascent populations that improve *A. campestris* var. *wormskioldii's* abundance and distribution.

Our review of the best available scientific and commercial information does not indicate that the potential stressors currently have, or are anticipated to have, population-level effects on *Artemisia campestris* var. *wormskioldii.* Some stressors cause or could cause individual mortality, including erosion, inundation, and possibly herbivory by native animals, but the available information does not indicate that any of, or the cumulative impact of all, these stressors has a population- or species-level impact now or that they are likely to have such impacts in the foreseeable future. Although numbers of mature, flowering individuals at some populations have decreased in recent years, numbers have increased at others. While questions remain regarding limiting factors, demography, age structure, and population trends, the plant's ability to persist appears greater than previously understood.

Future impacts of climate change may exacerbate stressors to *A. campestris* var. *wormskioldii* and its habitat, but we cannot reasonably project the timing, imminence, or severity of the effects of climate change into the foreseeable future. Further, the uncertainty about how *A. campestris* var. *wormskioldii* will respond to climate change, combined with the uncertainty about how potential changes in plant species composition would affect site suitability, make projecting possible synergistic effects of climate change highly speculative at this time.

A species may occur in very low numbers without being at risk of extinction. Such species, merely by virtue of their rarity, do not merit listing under the Act. Although *Artemisia campestris* var. *wormskioldii* has persisted at low numbers and with a narrowly limited distribution, rarity in itself does not automatically imply that the species is at risk of extinction. Moreover, a species may be exposed to stress factors and lose individuals, without expressing a negative response at the population or species level such that the species meets the definition of endangered or threatened under the Act. We must evaluate the exposure of the species to stressors to determine whether the species responds to the stressors in a way that causes impacts now or is likely to cause impacts in the future. We also must determine whether impacts are or will be of an intensity or magnitude to place the species at risk. In our analysis of potential stressors to *A. campestris* var. *wormskioldii,* we have not found evidence of such responses or negative impacts.

Finding

Based on our evaluation of the best available scientific and commercial information, we find that no stressors are of sufficient imminence, intensity, or magnitude to indicate that *A. campestris* var. *wormskioldii* is in danger of extinction (endangered) or likely to become endangered within the foreseeable future (threatened) throughout all of its range. This is because we have determined that threats we identified in past CNORs are not affecting the species as we previously understood. Further, the distribution of *Artemisia campestris* var. *wormskioldii* is relatively stable across its range (and the number of populations, including sites where the plant was recently introduced, has increased since 2006) and stressors are similar throughout the species' range. Thus, we did not find any concentration of stressors that suggests that this plant may be in danger of extinction in any portion of its range. Therefore, we find that listing *A. campestris* var. *wormskioldii* as an endangered or a threatened species is not warranted throughout all or a significant portion of its range at this time, and consequently we are removing this species from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for *Artemisia campestris* var. *wormskioldii,* and constitutes the Service's 12-month finding on the May 11, 2004, petition to list *A. campestris* var. *wormskioldii* as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the *A. campestris* var. *wormskioldii* 's species-specific assessment form and other supporting documents (see **ADDRESSES**, above).

Virgin Islands Coquí (*Eleutherodactylus schwartzi*)

Previous Federal Actions

On October 6, 2011, the Service received a petition dated September 28, 2011, from WildEarth Guardians, requesting that we list the Virgin Islands coquí (VI coquí), a frog species, under the Act. On January 22, 2014, we published a 90-day finding (79 FR 3559) in which we found that the petition presented substantial scientific and commercial information indicating that listing may be warranted for the VI coquí.

Background

The VI coquí is a small frog species, of the family Eleutherodactylidae. The VI coquí was first described as *Eleutherodactylus schwartzi* based on specimens obtained on the islands of Tortola and Virgin Gorda. While similar to the Puerto Rican coquí (*Eleutherodactylus coquí*), a species native to neighboring Puerto Rico, *E. schwartzi* is distinguished by its smaller size and coloration.

The VI coquí's breeding season begins in May and lasts until August. Although members of the *Eleutherodactylus* genus do not require an aquatic environment for reproduction, they do require cool, moist habitat for rehydration and to prevent the desiccation of egg clutches. This species is a "direct development" species, meaning that it skips the tadpole stage and fully formed froglets hatch from the eggs.

The VI coquí is a tree-dwelling, terrestrial species, occurring in temperate woodlands and forests, in elevations up to 227 meters (744.7 feet). The species is typically not found outside of forested areas. However, there have been reports of the VI coquí in residential gardens, pastures, and gullies in and around Great Harbour on the island of Jost Van Dyke and in residential gardens on Frenchman's Cay. The VI coquí prefers to hide under rocks, leaf litter, and bromeliad leaves during the day to stay out of the hot sun. The species is strongly associated with the presence of terrestrial bromeliads, such as the false pineapple (*Bromelia pinguin*) and species from the genus *Tillandsia*. The males use bromeliads for perching when calling, and females lay their eggs on the leaves of the plants.

The VI coquí has a broad diet that includes small vertebrates and invertebrates. Although there is a lack of information on the diet of this species, members of the genus *Eleutherodactylus* are known to be "nocturnal, sit-and-wait predators that prey on members of the order Hymenoptera (which includes ants, wasps, bees), Collembolan (springtails), Pseudoscorpionida (false scorpions) and Dipteran (true flies)".

The VI coquí has a relatively limited range, with its historical population occurring in the U.S. Virgin Islands (USVI) and the British Virgin Islands (BVI) in the Caribbean. Specifically, the species was found on the island of Saint John in the USVI and the islands of Tortola, Virgin Gorda, Jost Van Dyke, Great Dog, Beef Island, Frenchman's Cay, and Little Thatch in the BVI. The species has since experienced alteration of its range within the past 40 years. Surveys conducted in the 1970s found no presence of the species on St. John in the USVI, suggesting the species is extirpated there. Although some ambiguity exists in the survey due to similarity in calls between the VI coquí and the related Puerto Rican coquí, subsequent acoustic surveys confirmed the presence of the VI coquí on the other islands: Tortola, Virgin Gorda, Jost Van Dyke, Great Dog, Beef Island, and Frenchman's Cay.

Summary of Status Review

A supporting document entitled "12-Month Finding on a Petition to List the Virgin Islands Coquí as an Endangered or Threatened Species" provides a summary of the current literature and information regarding the VI coquí's distribution, habitat requirements, life history, and stressors (see **ADDRESSES**, above). We reviewed the petition, information available in our files, and other available published and unpublished information, and we consulted with recognized species and habitat experts and representatives of the range countries.

We evaluated whether each of the potential stressors impact, presently or in the future, individuals or portions of suitable habitat. The potential stressors that we assessed are: (1) Habitat loss and fragmentation from urban development; (2) trade and collection; (3) predation from the small Indian mongoose and Cuban tree frog (CTF); (4) chytridiomycosis; (5) inadequacy of existing regulatory mechanism; (6) competition from CTF and Puerto Rican coquí; (7) climate change; and (8) small population size.

The Virgin Islands coquí is found on six islands in the BVI. Although we do not have survey data on the population, the species continued to persist on these islands. Continued persistence of the species on the island is due to past and present management efforts by the BVI territory government. Rate of deforestation has declined from historical high in the 20th century due to the transition in the BVI's economy from cash crop to tourism as well as the establishment of protected areas. These protected areas helped maintain and protect remaining forest habitats. Additionally, these areas have allowed deforested habitat to recover, promoting new secondary deciduous and dry forests.

To support the BVI tourism industry, development projects are being proposed or are currently in progress across the BVI with Tortola containing most of the major projects. However, most of the development projects occur in areas that already contain little to no coquí habitat; therefore we have no reason to believe that these projects would adversely affect the VI coquí. We also found no indications of trade or collection occurring with this species.

The impact of invasive species such as the small Indian mongoose and the CTF is mitigated both by ongoing management effort as well as differences in the ecology of these species. A mongoose eradication program is currently in place on Jost Van Dyke. The small Indian mongoose's preference for drier climate gives the coquí some protection from predation, as it prefers wetter habitat. More importantly, mongoose cannot climb trees, which offers protection for arboreal species like the coquí. These factors together limit the impact the mongoose has on the VI coquí.

The impact of CTF on the VI coquí is ameliorated by differences in reproductive method and ongoing management program. CTF require freshwater habitat to lay their eggs. Meanwhile, as a direct-developing species, VI coquí can give birth to live young in bromeliads. Additionally, predation of VI coquí by CTF is limited due to CTF's preference for smaller invertebrates, with frogs making up only 3 percent of CTF's diet. CTFs may compete with VI coquís for prey, as the species' diet is similar to the coquí's. However, we have found no information indicating competition for invertebrates is affecting the coquí.

The impact of chytrid fungus on the VI coquí is limited by local conditions in the BVI. The current temperature range in the BVI is outside the optimal range of the fungus. Additionally, while cases of infection can still occur in sub-optimal area, infection may not be fatal due to unfavorable growing conditions of the fungus.

We reviewed all international and local laws, regulations, and other regulator mechanisms that may impact the VI coquí and its habitat. Despite shortages in staff and personnel, a recent survey of protected areas found many areas to be stable or experiencing light development. The stability in these protected areas seems to indicate that although these organizations are facing shortages in funds and staff, they are still able to protect fragile habitat in the BVI.

Surveys conducted on Jost Van Dyke found the Puerto Rican coquí may also compete with the VI coquí. Although the potential exists that the Puerto Rican coquí could compete with the VI coquí, sightings of the species have only recently occurred on Jost Van Dyke in 2015. The Puerto Rican coquí has not been documented on the other six islands where the VI coquí is known to occur. Thus, it is too soon to tell what impacts, if any, the Puerto Rican coquí might have on the VI coquí.

The effects of climate change on the VI coquí are unclear. While the impact from an increase in stochastic event is limited by the steep hills and mountains on the islands, the impact of climate change on plant biomes and the species' reproductive season remains unknown. As we do not have information to reasonably predict whether climate change may affect the species' breeding season or result in changes in plant composition, we cannot draw conclusions on how the VI coquí may respond to potential changes.

While we do not have information on population trends for the VI coquí, we nonetheless considered whether small population size and limited distribution in combination with other stressors might impact the species. The species has been described as rare. However, species that naturally occur in low densities are not necessarily in danger of extinction, and therefore do not necessarily warrant listing, merely by virtue of their rarity. In the absence of information identifying stressors to the species and linking those stressors to the rarity of the species or a declining status, we do not consider rarity alone to be a threat. Further, a species that has always had small population sizes or has always been rare, yet continues to survive, could be well-equipped to continue to exist into the future.

Finally, we found that the VI coquí has sufficient resiliency, redundancy and representation to recover from periodic disturbance such as hurricanes, droughts, and other stochastic events. The VI coquí population is distributed across six of nine islands in the BVI, which contributes to the redundancy of the species. While we lack detailed information on the genetic diversity of the species, male VI coquís on different islands are characterized by variation in sizes. Additionally, the Great Dog population of VI coquí has been described as somewhat distinct. These factors suggest that there exist genetic diversity (representation) among the populations of coquí across the six islands.

Finding

Based on our review of the best available scientific and commercial information pertaining to the five factors, we find that the stressors acting on the species and its habitat, either singly or in combination, are not of sufficient imminence, intensity, or magnitude to indicate that the VI coquí is in danger of extinction (endangered) or likely to become endangered within the foreseeable future (threatened), throughout all or a significant portion of its range.

We found no portions of the species' range where potential threats are significantly concentrated or substantially greater than in other portions of its range. Therefore, we find that factors affecting the species are essentially uniform throughout its range, indicating no portion of the range of the VI coquí is likely to be in danger of extinction or likely to become so within the foreseeable future. Therefore, we found that no portion warranted further consideration to determine whether the species may be endangered or threatened in a significant portion of its range.

Therefore, we find that listing the VI coquí as an endangered or threatened species under the Act is not warranted at this time. This document constitutes the 12-month finding on the September 28, 2011, petition to list the VI coquí as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the supporting document entitled "12-Month Finding on a Petition to List the Virgin Islands Coquí as an Endangered or Threatened Species" (see **ADDRESSES**, above).

Washington Ground Squirrel (*Urocitellus washingtoni*)

Previous Federal Actions

The Washington ground squirrel was recognized as a Category 2 candidate species (as *Spermophilus washingtoni*) in 1994 (59 FR 58982; November 15, 1994). When the February 28, 1996, CNOR (61 FR 7596) discontinued recognition of categories, the Washington ground squirrel was no longer considered a candidate species. We again identified the Washington ground squirrel as a candidate for listing in 1999 (64 FR 57534; October 25, 1999) and assigned a listing priority number of 5, which reflects threats of a high magnitude that are not considered imminent.

On March 2, 2000, we received a petition from the Northwest Environmental Defense Center, Defenders of Wildlife, and the Oregon Natural Desert Association to emergency list the Oregon population of this species as a distinct population segment, or list the species over its entire range as an endangered or threatened species under the Act. Included in the petition was information regarding the species' taxonomy and ecology, historical and current distribution, present status, and actual and potential causes of decline. In 2001, based on new information, including information contained in the 2000 petition, we determined that the Washington ground squirrel faced imminent threats of a high magnitude and reassigned it an LPN of 2 (66 FR 54808; October 30, 2001). The Washington ground squirrel remained on the candidate list with an LPN of 2 from 2002 to 2004 (67 FR 40657, June 13, 2002; and 69 FR 24876, May 4, 2004). In the 2005 CNOR (70 FR 24870, May 11, 2005), we changed the LPN to 5, and since that date, the species has remained on the candidate list with an LPN of 5 (71 FR 53756, September 12, 2006; 72 FR 69034, December 6, 2007; 73 FR 75176, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; and 80 FR 80584, December 24, 2015). In our November 22, 2013, CNOR (78 FR 70104), we recognized *Urocitellus washingtoni* as the scientific name for the Washington ground squirrel.

Background

The Washington ground squirrel was formerly part of the genus *Spermophilus* (as *Spermophilus washingtoni*), but is now determined to be one of 12 species in the genus *Urocitellus* (Holarctic ground squirrels. The Washington ground squirrel is diurnal (active during the day) and semi-fossorial (*e.g.*, partly adapted to digging and life underground). Their active, above-ground period spans anywhere between the months of January and July, with the specific timing depending on elevation and microhabitat conditions as well as availability of food sources. Washington ground squirrels typically live fewer than 5 years and produce one litter annually, with an average of five to eight pups. They eat a wide variety of foods including succulent forbs and grass stems, buds, leaves, flowers, roots, bulbs, and seeds.

The Washington ground squirrel occurs in shrub-steppe and grassland habitat in eastern Washington and north-central Oregon. In Washington, the species occurs in Adams, Douglas, Franklin, Grant, Lincoln, and Walla Walla Counties. In Oregon, it is found in Gilliam, Morrow, and Umatilla Counties, but is centered largely on the Naval Weapon Systems Training Facility Boardman (NWSTF Boardman) and the adjacent Boardman Conservation Area (BCA). Washington ground squirrel habitat is characterized by deep, loamy soils deposited by the Missoula Floods and shrub-steppe vegetation. Historically, the species was primarily associated with sagebrush (*Artemisia* sp.) and bunchgrass habitats, but cheatgrass (*Bromus tectorum*) and rabbitbrush (*Chrysothamnus* sp.) have replaced much of the original flora on nonagricultural land. The species can be found in all these habitat types where there is sufficient forage and suitable soils, regardless of vegetation type.

Summary of Status Review

Historically, the Washington ground squirrel was a little-studied species. A 1990 survey of 179 of the 189 potential historical Washington ground squirrel locations found 80 confirmed and 7 probable colonies. In a repeat survey in 1998 of the confirmed and probable sites, clear evidence of squirrels was found at only 46 of the locations. The Washington ground squirrel received more attention and funding after it became a Federal candidate species in 1999, and the increased survey effort led to a notable expansion of the number of documented locations and distribution of the species from what was known in 1999.

As part of our assessment of the best available scientific and commercial information, we evaluated the number of Washington ground squirrel records included in the Oregon and Washington Natural Heritage Program databases. In Oregon, 2012 data showed 705 known records (any of which could constitute a single individual or a small, medium, or large colony). As of April 2013, Oregon records of Washington ground squirrels had increased to 1,318, an 87 percent increase from the 2012 data. In Washington, 2012 data showed 567 mapped polygons (estimated areas containing squirrels) and 65 known squirrel records outside of the polygons. As of April 2013, Washington polygons had increased to 602 and records had increased to 579.

These updated Washington ground squirrel records, along with new information on dispersal distances and habitat quality, led us to evaluate potential connectivity between squirrel detections. We analyzed new data regarding linkages between areas of high-quality habitat, and dispersal distances from known sites to potential habitat, and found that there is some connectivity between these areas of high-quality habitat, and connectivity between known sites and potential habitat. The majority of known Washington ground squirrel sites are on public lands, within the BCA, or are newer sites documented from increased survey efforts on private lands. The analysis indicated that many squirrel sites are within dispersal distance of one another, and potential squirrel habitat exists within the interstitial space between clusters providing connectivity between the sites. This indicates that Washington ground squirrel populations are not as isolated from one another as we had previously thought, and potential opportunities for genetic exchange exist in most of the range, as many sites are likely functioning within a metapopulation framework.

Furthermore, based on the Washington Wildlife Habitat Connectivity Working Group habitat quality layer for Washington ground squirrel and recent squirrel surveys in Oregon and Washington, we estimated that there are at least 0.74 million hectares (ha) (1.84 million acres (ac)) of potential occupied habitat within the current range. Although our finding does not rely on the presumed presence of squirrels in potential habitat, this estimate of potential habitat, along with the fact that new sites are consistently documented when suitable habitat is surveyed, supports the assumption that additional Washington ground squirrels are likely to be found with further survey effort in large areas of at least moderate-quality potential habitat. This adds confidence to our independent conclusion that, based on the best scientific data currently available to us, the Washington ground squirrel is more widespread and numerous than we had previously understood.

Candidate status was based on habitat loss, fragmentation, or modification due to fire and invasive plants, agriculture, intensive grazing, proposed and ongoing military activities, energy development and transmission, and urban development; predation; recreational shooting; disease; potential effects of pesticides; and potential effects of drought on forage quality and quantity. Habitat loss was considered the main reason the squirrel's range is smaller than it was historically, particularly through agricultural conversion of shrub-steppe habitat, and more recently the invasion of nonnative annual grasses and forbs, especially cheatgrass.

There are current management actions, policies, and protections in place that have substantially reduced or eliminated stressors to the Washington ground squirrel and will continue to do so in the future. The 25-year Threemile Canyon Farms Multi-Species Candidate Conservation Agreement with Assurances (MSCCAA), signed in 2004, included the implementation of habitat management, operational modifications, and conservation measures for four unlisted species, including the Washington ground squirrel, on approximately 37,636 ha (93,000 ac) of habitat. This dramatically reduced agricultural development in Washington ground squirrel habitat and was part of an overall decline in the conversion of shrub-steppe to agricultural use in recent years; harvested cropland accounted for only 1 percent of all land available to the squirrel within its range during the 1978 to 2007 time period. There are no known large-scale agricultural projects planned that are likely to impact Washington ground squirrels by conversion to agricultural uses, and we are unaware of any planned U.S. Department of Agriculture programs that could significantly change the current rate of conversion in counties containing Washington ground squirrels in the future. Furthermore, as a State-endangered species in Oregon, activities detrimental to squirrels are prohibited on State-owned or leased land and easements in Oregon. The Oregon Energy Facility Siting Council and Gilliam, Morrow, and Umatilla Counties have adopted the State's guidelines on 100 percent of wind projects sited in Oregon, and these guidelines include conservation measures for Washington ground squirrels. Urban development, while it continues, is mostly concentrated in urban growth areas, which represent a very small portion of the range. Finally, the Service and Foster Creek Conservation District (FCCD) signed the Douglas County Multiple Species General Conservation Plan (MSGCP) on September 17, 2015. The MSGCP is a programmatic habitat conservation plan that private landowners in Douglas County, Washington, can voluntarily opt into; the plan includes best management practices (BMPs) specific to supporting the conservation of Washington ground squirrels. Though this habitat conservation plan is anticipated to provide conservation benefits to Washington ground squirrel, it is a voluntary program and we do not know how many landowners will enroll, so we cannot rely on the certainty of these benefits in our finding determination.

We also evaluated a future conservation effort in connection with military readiness activities at NWSTF Boardman following the Service's *Policy for Evaluation of Conservation Efforts When Making Listing Decisions* (PECE); 68 FR 15100, March 28, 2003). The final environmental impact statement (FEIS) completed in December 2015, and record of decision (ROD) signed on March 31, 2016, confirm the Navy's commitment to implement conservation efforts that eliminate or reduce threats to Washington ground squirrels from military readiness activities on the 19,020 ha (47,000 ac) of NWSTF Boardman through a combination of BMPs, mitigation, monitoring, and adaptive management. In order to determine whether we should consider these conservation measures in this decision, we completed an analysis of the certainty of implementation and effectiveness of these future actions pursuant to PECE (68 FR 15100; March 28, 2003). Based on the history of the Navy's collaboration with us; the combined application of BMPs, mitigation, monitoring, and adaptive management; and their formal commitment to fully implement the actions they agreed to, we have a high level of certainty that the conservation efforts will be implemented and effective, and therefore considered them in this determination for the Washington ground squirrel. Military readiness activities at NWSTF Boardman will negatively impact only a small percentage (less than 1 percent) of the Washington ground squirrel habitat on the facility. Additionally, the majority of impacts associated with projectiles striking the ground, potential training-caused wildfires, and spread of invasive plants would occur in a small area (less than 324 ha (800 ac)). The Navy has committed to implementing all of the BMPs, mitigation measures, and the adaptive management strategy outlined in their FEIS in order to ameliorate any impacts to the species due to current and future military readiness activities. Therefore, we consider the former threat posed to Washington ground squirrels from military readiness activities to have been ameliorated.

Fire and conversion of sagebrush habitat to invasive plant species are, and will continue to be, rangewide issues. However, fire and invasive species have not prevented squirrels from persisting and remaining broadly distributed in these habitats, even in areas that burn frequently (*e.g.*, the NWSTF), and we anticipate squirrels will continue to persist in these areas. These stressors are being addressed at varying levels by landowners, local governments, organizations, and agencies. Grazing can be a compatible land use with this species, and we have no information indicating that intensive grazing is currently widespread, or anticipated to be in the future, in areas occupied by the species. Other factors such as shooting, disease, and effects from pesticide use occur on a small enough scale that they are not considered significant stressors to the species now, nor are they likely to be in the future.

Some isolated populations of the Washington ground squirrel may be vulnerable to genetic effects associated with small populations; however squirrel occurrence sites are likely not as isolated as we previously thought. The rate of habitat conversion that contributes to habitat fragmentation has dropped significantly, and there are no strong and predictive trends toward development or agricultural conversion of occupied and potential habitat. Furthermore, we have documentation that squirrels are more widely distributed than previously thought; it is very likely that additional undocumented sites exist and connectivity provides potential opportunities for genetic exchange in most of the range. We therefore conclude that small population size is not currently a stressor to the Washington ground squirrel as a whole, nor is it likely to become one in the future.

Washington ground squirrel habitat is likely to be influenced by the climate change effects of increased temperatures, changes in precipitation, increased frequency and intensity of fire, and an increase in invasive vegetation (due to fire, drought, and increased carbon dioxide concentrations). We have some information about climate-change projections for temperature and precipitation in the range of the squirrel, but we have no information to suggest that temperature will increase or precipitation decrease to levels that would affect the viability of Washington ground squirrels rangewide. Increased winter and spring precipitation could have a positive effect on squirrels by providing adequate forage during the breeding season. Although hotter and drier summers may reduce the quality and abundance of native forage available to Washington ground squirrels, the species is distributed across a range of elevations, has a diverse diet, and is able to persist in disturbed grassland. Thus, the best available scientific and commercial information at this time does not lead us to conclude that the current or future effects of climate change will impact the viability of Washington ground squirrels rangewide.

Finding

Based on our review of the best available scientific and commercial information pertaining to the five factors, and when considering all of the factors in combination with each other and the existing conservation measures that benefit the species and its habitat, we conclude that the impacts on the species and its habitat are not of such imminence, intensity, or magnitude to indicate that the Washington ground squirrel is in danger of extinction (an endangered species), or likely to become so within the foreseeable future (a threatened species), throughout all of its range. Although the types of stressors vary across the range, we found no portion of its range where the stressors are significantly concentrated or substantially greater than in any other portion of its range. Therefore, we find that listing the Washington ground squirrel as an endangered or threatened species or maintaining the species as a candidate is not warranted throughout all or a significant portion of its range at this time, and consequently we are removing it from candidate status.

As a result of the Service's 2011 multidistrict litigation settlement with the Center for Biological Diversity and WildEarth Guardians, the Service is required to submit a proposed listing rule or a not-warranted 12-month finding to the **Federal Register** by September 30, 2016 (In re: Endangered Species Act Section 4 Deadline Litigation, No. 10–377 (EGS), MDL Docket No. 2165 (D.D.C. May 10, 2011)), for all 251 species that were included as candidate species in the Service's November 10, 2010, CNOR. This document satisfies the requirements of that settlement agreement for the Washington ground squirrel and constitutes the Service's 12-month finding on the March 2, 2000, petition to list the Washington ground squirrel as an endangered or threatened species. A detailed discussion of the basis for this finding can be found in the Washington ground squirrel's species-specific assessment form and other supporting documents (see **ADDRESSES**, above).

New Information

We request that you submit any new information concerning the taxonomy, biology, ecology, status of, or stressors to the angular dwarf crayfish, Guadalupe murrelet, Huachuca springsnail, two Kentucky cave beetles (Clifton Cave and Icebox Cave beetles), *Artemisia campestris* var. *wormskioldii,* Scripps's murrelet, Virgin Islands coquí, and Washington ground squirrel to the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**, whenever it becomes available. New information will help us monitor these species and encourage their conservation. We encourage local agencies and stakeholders to continue cooperative monitoring and conservation efforts for these species. If an emergency situation develops for these species, we will act to provide immediate protection.

References Cited

Lists of the references cited in the petition findings are available on the Internet at *http://www.regulations.gov* and upon request from the appropriate person, as specified under **FOR FURTHER INFORMATION CONTACT**.

Authors

The primary authors of this document are the staff members of the Unified Listing Team, Ecological Services Program.

Authority

The authority for this section is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 7, 2016.

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2016–22453 Filed 9–20–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2016–0037; 4500030113]

RIN 1018–BB55

Endangered and Threatened Wildlife and Plants; Threatened Species Status for Pearl Darter

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Pearl darter (*Percina aurora),* a fish from Mississippi, as a threatened species under the Endangered Species Act (Act). If we finalize this rule as proposed, it would extend the Act's protections to this species. The effect of this proposed regulation will be to add this species to the List of Endangered and Threatened Wildlife.

DATES: We will accept comments received or postmarked on or before November 21, 2016. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by November 7, 2016.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R4–ES–2016–0037, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on "Comment Now!"

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R4–ES–2016–0037; U.S. Fish and Wildlife Service Headquarters, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see *Public Comments* below for more information).

FOR FURTHER INFORMATION CONTACT: Stephen Ricks, Field Supervisor, U.S. Fish and Wildlife Service, Mississippi Ecological Services Field Office, 6578 Dogwood Parkway, Jackson, Mississippi 39213, by telephone 601–321–1122 or by facsimile 601–965–4340. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if we determine that a species is an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within one year. Listing a species as an endangered or threatened species can only be completed by issuing a rule.

What this document does. This document proposes the listing of the Pearl darter *(Percina aurora)* as a threatened species. The Pearl darter is a candidate species for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which until now development of a listing regulation has been precluded by other higher priority listing activities. This proposed rule reassesses all available information regarding status of and threats to the Pearl darter.

This document does not propose critical habitat for the Pearl darter. We have determined that critical habitat is prudent, but not determinable at this time.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that water quality decline from point and nonpoint source pollution continues to impact portions of this species' habitat. In addition, geomorphology changes attributed to past sand and gravel mining operations within the drainage are considered an ongoing threat. This species has been extirpated from the Pearl River watershed and is confined today to the Pascagoula River Basin where this species' small population size and apparent low genetic diversity increases its vulnerability to extirpation from catastrophic events.

We will seek peer review. We will seek comments from independent specialists to ensure that our designation is based on scientifically sound data, assumptions, and analyses. We will invite these peer reviewers to comment on our listing proposal.

Information Requested

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from the public, other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The Pearl darter's biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is a threatened or endangered species must be made "solely on the basis of the best scientific and commercial data available."

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Mississippi Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Because we will consider all comments and information received during the comment period, our final determinations may differ from this proposal.

Public Hearing

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we have sought the expert opinions of three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our listing determination is based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise in the Pearl darter's biology, habitat, and physical or biological factors that will inform our determination.

Previous Federal Actions

We identified the Pearl darter (Pearl channel darter, *Percina* sp.) as a Category 2 Candidate in the November 21, 1991, Animal Candidate Review for Listing as Endangered or Threatened Species; Notice of Review (56 FR 58804). Category 2 Candidates were defined as species for which we had information that proposed listing was possibly appropriate, but conclusive data on biological vulnerability and threats were not available to support a proposed rule at the time. The species remained so designated in the subsequent November 15, 1994, annual Candidate Notice of Review (CNOR) (59 FR 58982). In the February 28, 1996, CNOR (61 FR 7596), we discontinued the designation of Category 2 species as candidates; therefore, the Pearl darter was no longer a candidate species.

Subsequently, in 1999, the Pearl darter was once again added to the candidate list (64 FR 57534, October 25, 1999). Candidates are now defined as those fish, wildlife, and plants for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing regulation is precluded by other higher priority listing activities. The Pearl darter was included in all of our subsequent annual CNORs: 66 FR 54808, October 30, 2001; 67 FR 40657, June 13, 2002; 69 FR 24876, May 4, 2004; 70 FR 24870, May 11, 2005; 71 FR 53756, September 12, 2006; 72 FR 69034, December 6, 2007; 73 FR 75176, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; 76 FR 66370, October 26, 2011; 77 FR 69994, November 21, 2012; 77 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; 80 FR 80584, December 24, 2015.
The Pearl darter has a listing priority number of 8, which reflects a species with threats that are both imminent and moderate to low in magnitude.

On May 11, 2004, we were sent a petition to list the Pearl darter by the Center for Biological Diversity. Because no new information was provided in the petition, and we had already determined the species warranted listing, no further action was taken on the petition.

On May 10, 2011, the Service announced a work plan to restore biological priorities and certainty to the Service's listing process. As part of an agreement with one of the agency's most frequent plaintiffs, the Service filed a work plan with the U.S. District Court for the District of Columbia. The work plan enables the agency to, over a period of 6 years, systematically review and address the needs of more than 250 species listed within the 2010 CNOR, including the Pearl darter, to determine if these species should be added to the Federal Lists of Endangered and Threatened Wildlife and Plants. This work plan enables the Service to again prioritize its workload based on the needs of candidate species, while also providing State wildlife agencies, stakeholders, and other partners clarity and certainty about when listing determinations will be made. On July 12, 2011, the Service reached an agreement with another frequent plaintiff group and further strengthened the work plan, which allows us to focus our resources on the species most in need of protection under the Act. These agreements were approved by the court on September 9, 2011. The timing of this proposed listing is, in part, an outcome of the work plan.

Background

Taxonomy and Species Description

The Pearl darter (*Percina aurora*) is a small fish with a blunt snout, horizontal mouth, large eyes located high on the head, and a medial black spot at the base of the caudal (tail) fin (Ross 2001,

p. 498). Described in 1994 (Suttkus *et al.* 1994, pp. 13–17) from the Strong River in Simpson County, MS (Ross 2001, p. 500), the Pearl darter is one of three members of the subgenus *Cottogaster.* The Pearl darter is closely allied to the channel darter (*P. copelandi*) (Ross *et al.* 1989, p. 25). It is distinguished from the channel darter by its larger body size, lack of tubercles (small, raised, skin structures) and heavy pigmentation of breeding males, high number of marginal spines on the belly scales of breeding males, and fully scaled cheeks. Breeding males have two dark bands across the spinous dorsal (back) fin, a broad, diffuse, dusky marginal band, and a pronounced dark band across the fin near its base. Breeding females lack pigmentation on their ventral body surface. The Pearl darter reaches a maximum standard length (SL) of 57 millimeters (mm) (2.2 inches (in.)) in females and 64 mm (2.5 in.) in males (Suttkus *et al.* 1994, p. 16).

Distribution

Historical Range

The Pearl darter is historically known from localized sites within the Pearl and Pascagoula River drainages of Mississippi and Louisiana, based on collection records from 16 counties/parishes of Mississippi and Louisiana. The quantified range of the Pearl darter, expressed in river miles, has not been well-defined by researchers (Slack *et al.* 2005, pp. 5–10; Ross 2001, p. 499; Ross *et al.* 2000, pp. 5–8; Bart and Piller 1997, pp. 3–10; Bart and Suttkus 1996, pp. 3–4, Suttkus *et al.* 1994, pp. 15–18). However, a recent reanalysis of collection records compiled from the Mississippi Museum of Natural Science (MMNS) (2016, unpublished data) estimates the species' historical range to be approximately 708 kilometers (km) (440 miles (mi)) in the Pearl River and 539 km (335 mi) in the Pascagoula River system, for a total historical range of 1,247 km (775 mi).

Pearl River Watershed—Examination of site records of museum fish collections from the Pearl River drainage (compiled from Suttkus *et al.* 1994, pp. 15–18) suggest that the darter once inhabited the large tributaries and main channel habitats from St. Tammany Parish, LA, to Simpson County, MS. This area included approximately 364 km (226 mi) of the lower Pearl River, 21 km (13 mi) of the Strong River, and 322 km (200 mi) of Bogue Chitto River for a total of approximately 708 km (440 mi), all of which is below the Ross Barnett Reservoir (compiled from MMNS 2016, unpublished data; Slack *et al.* 2005, pp. 5–10; Ross 2001, p. 499; Ross *et al.* 2000, pp. 2–5, Bart and Piller 1997, pp. 3–10; Bart and Suttkus 1996, pp. 3–4; Suttkus *et al.* 1994, pp. 15–18).

Despite annual collection efforts by Suttkus from 1958 to 1973 (Bart and Suttkus 1996, pp. 3–4; Bart and Suttkus 1995, pp. 13–14; Suttkus *et al.* 1994, pp. 15–18), the Pearl darter was collected from only 14 percent of 716 fish collections from site-specific locations within the Pearl River drainage. There have been no records of Pearl darters from the Pearl River drainage since 1973, despite Suttkus' 64 fish collections from this time through the middle 1990s from the Pearl River (Bart and Piller 1997, p. 1) and other various collection efforts in the lower Pearl River system (Roberts 2015, pers. comm.; Slack *et al.* 2005, pp. 5–10; Ross 2001, p. 499). There are no records of Pearl darters in the upper Pearl River system (upstream of the Ross Barnett Dam), and collection efforts by Schaefer and Mickel in 2011 (p. 10) confirmed its absence from this part of the Pearl River. A recent survey at the type locality in the Strong River verified its absence from that area also (Roberts 2015, pers. comm.). There have been no verifiable records of the Pearl darter from the Pearl River drainage in over 40 years, thus, this species is considered extirpated from that system, representing a 57 percent loss of its historical range.

Pascagoula River Watershed—Site records from museum fish collections before 2005 suggested that the Pearl darter inhabited the main channels of large Pascagoula drainage tributaries from Jackson to Lauderdale Counties (Ross 2001, pp. 499–500). Although collection data from Ross (2001, p. 500), Bart and Piller (1997, p. 4), Bart and Suttkus (1996, p. 4), and Suttkus *et al.* (1994, p. 19) suggested that the Pearl darter was very rare in the Pascagoula River system. Bart and Piller (1997, p. 4) examined Suttkus' work before 1974 and found that only 19 Pearl darters were collected out of 19,300 total fish in 10 Tulane University Museum of Natural History collections. Additionally, from the Mississippi Freshwater Fishes Database, Ross (in Bart and Piller 1997, p. 4) estimated the rarity of the Pearl darter within the Pascagoula drainage from 379 collections (81,514 fish specimens) since 1973 and found that only one Pearl darter was collected for every 4,795 specimens. This species' historical range within the Pascagoula River system totaled approximately 539 km (335 mi), which included 48 km (30 mi) of the Pascagoula River, 11 km (7 mi) of Black Creek, 131 km (82 mi) of the Leaf River, 34 km (21 mi) of Okatoma Creek, 262 km (163 mi) of the Chickasawhay River, 39 km (24 mi) of the Bouie River, and 13 km (8 mi) of Chunky Creek (compiled from MMNS 2016 unpublished data; Slack *et al.* 2005, pp. 5–10; Ross 2001, p. 499; Ross *et al.* 2000, pp. 1–28; Bart and Piller 1997, pp. 3–10; Bart and Suttkus 1996, pp. 3–4; Suttkus *et al.* 1994, p. 19; Ross *et al.* 1992, pp. 2–10).

Current Range and Population Size

Today, Pearl darters are thought to occur only in scattered sites within approximately 449 km (279 mi) of the Pascagoula drainage, including the Pascagoula, Chickasawhay, Chunky, Leaf, and Bouie Rivers, and Okatoma and Black Creeks. In recent years, the species has been found sporadically within the Pascagoula, Chickasawhay, and Leaf Rivers. There have been no collecting attempts within the Bouie and Chunky Rivers, nor Okatoma and Black Creeks, in the last 15 years; thus, the status of populations in those systems is unknown.

Collections of Pearl darters over the last 20 years in the Pascagoula River drainage have included: 10 Pearl darters from 4 sites out of 27 fish collections in 1996 and 1997 from the Pascagoula River (Bart and Piller 1997, p. 3); 3 specimens from the Leaf River in 1998; and 7 collections (total of 45 Pearl darters) in the Pascagoula River at the confluence with Big Black Creek (Dead Lake) and downstream of Dead Lake for 22 km (14 mi) (Slack *et al.* 2002, p. 15). Slack *et al.* (2005, p. 5) sampled for Pearl darters within the Leaf and Chickasawhay rivers beginning near the confluence with the Pascagoula River and extending through portions of the Chickasaway and Leaf Rivers. The species was present in 78 localities among the 2 systems but were typically in low abundance when present. These survey efforts by Slack *et al.* (2005, pp. 1–15) indicated range of the Pearl darter within the Pascagoula drainage system was further upstream than previously known.

Over the last 15 years, Pearl darters have been found from late summer through fall in the upper Pascagoula River drainage (Leaf and Chickasawhay Rivers) and in the lower Pascagoula River proper in spring and summer (Clark and Schaeffer 2015, pp. 3, 9–10, 19, 23; Slack *et al.* 2002, p. 8). Young of Year (YOY) (fish from the current breeding season) were collected in both 2013 and 2014 in the Chickasawhay and Leaf Rivers, indicating the existence of reproducing populations and recruitment in both of those systems (Clark and Schaeffer 2015, pp. 10, 19, 23). Schaefer and Mickle (2011, pp. 1–

3) highlighted similarities in numbers of Pearl darters collected historically from the Pascagoula River Basin museum collections from 2000 to 2009 and found them to trend closely with the CPUE (Catch per Unit Effort) of 1980 to 1999 collections. Clark and Schaefer (2015, pp. 5, 9) recently resampled collection sites of Slack *et al.* (2005, pp. 1–13) in the Leaf and Chickasawhay Rivers, within the upper Pascagoula River, and found CPUE similar between the 2004 and 2014 surveys. Together, Clark and Schaefer (2015, pp. 5, 9), Schaefer and Mickle (2011, pp. 1–3) and Slack *et al.* (2005, pp. 1–13) suggest a stable population of Pearl darters has existed within these rivers in the upper Pascagoula River Basin over the last decade and speculate that populations may exist in small numbers within the other systems not recently sampled (*e.g.*, Chunky and Bouie Rivers, Okatoma and Black creeks).

Habitat

The Pearl darter occurs in low-gradient, coastal plain rivers (Suttkus *et al.* 1994, p. 13). The species is considered rare and is infrequently collected; however, its preference for deep water, main channels, and its association with woody debris accumulations can make sampling difficult (Bart and Piller 1997, p. 1). Pearl darters have been collected from gravel riffles and rock outcrops; deep runs over gravel and sand pools below shallow riffles; swift (90 cm per sec (35 in. per sec)), shallow water over firm gravel and cobble in mid-river channels; and swift water near brush piles. Slack *et al.* (2002, p. 10) found Pearl darters associated with scour holes on the inside bend of the river downstream from point bars and in substrata of coarse sand with detritus in troughs perpendicular to the shore line. Other collectors (Clark and Schaefer, 2015, pp. 11, 12, 19; Slack *et al.* 2005, p. 9; Bart and Piller 1997, p. 10) have found Pearl darters in areas with finer substrate (*i.e.*, loose sand, mud, silt), including a collection in loose detritus formed from a large scouring flood event (Clark and Schaefer 2015, p. 19). Very little aquatic vegetation was found in the areas where Slack *et al.* (2005, p. 9) collected the species.

Biology

Very little is known about the reproductive biology and general ecology of the Pearl darter (Ross 2001, p. 499). Most Pearl darters mature in 1 year. Female Pearl darters are sexually mature at 39 mm (1.5 in) SL, while males are mature at 42 mm (1.7 in.) SL (Suttkus *et al.* 1994, pp. 19–20). Breeding males have been observed during May in shallow water (15 cm (5.9 in.)) over firm gravel and cobble in mid channel in water temperatures from 17 to 21 degrees Celsius (°C) (62.6 to 69.8 degrees Fahrenheit (°F)) (Bart and Piller 1997, p. 9; Suttkus *et al.* 1994, p. 19). It is thought that subadult Pearl darters migrate upstream during the fall and winter to spawn in gravel reaches (Bart *et al.* 2001, p. 14). Spawning of Pearl darters in the Pearl and Strong Rivers (Mississippi) has been documented during March through May in the upper reaches of the Bogue Chitto River (Mississippi and Louisiana) (Suttkus *et al.* 1994, pp. 19–20). YOY Pearl darters were collected in June from the Pearl River (Suttkus *et al.* 1994, p. 19). Bart and Pillar (1997, pp. 6–7) described the Strong River rapids area, near the geological outcroppings, as an important historical spawning habitat for the species in the Pearl River system.

Summary of Biological Status and Threats

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations in title 50 of the Code of Federal Regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination. Each of these factors is discussed below:

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

All members of *Cottogaster* are undergoing range contractions and are of potential conservation concern throughout their respective distributions (Dugo *et al.* 2008, p. 3; Warren *et al.* 2000, pp. 7–8; Goodchild 1994, pp. 433–435). The Pearl darter has been extirpated from the Pearl River drainage, representing an approximately 57 percent loss of its historical range. Suttkus *et al.* (1994, p. 19) attributed the loss of the Pearl darter in the Pearl River to increasing sedimentation from habitat modification caused by the removal of riparian vegetation and extensive cultivation near the river's edge. In addition, the decline of the species in the Pearl River was likely exacerbated by the construction of low sill dams by the West Pearl Navigation Waterway, which blocked fish passage and is thought to have led to the extirpation of the Alabama shad (*Alosa alabamae*) from the system (Mickel *et al.* 2010, p. 158).

Water Quality Degradation

Similar to the Pearl River system, the Pascagoula River system suffers from acute and localized water quality degradation by nonpoint source pollution in association with land surface, stormwater, and effluent runoffs from urbanization and municipal areas (Mississippi Department of Environmental Quality (MDEQ) 2005c, p. 23; 2005d, p. 16). TMDLs (Total Maximum Daily Loads; regulatory term in the U.S. Clean Water Act describing a benchmark set for a certain pollutant to bring water quality up to the applicable standard) have been established for 89 segments of the Pascagoula River Basin, many of which include portions of the Pearl darter's range (MDEQ 2014a, pp. 18–21). For sediment, one of the most pervasive pollutants, the State of Mississippi has TMDLs for various tributaries and main stems of the Leaf and Chickasawhay Rivers. To date, efforts by the State of Mississippi to improve water quality in the Pascagoula River basin to meet these TMDL benchmarks have been inadequate (MDEQ 2014a, pp. 18–21). Thirty-nine percent of the Pascagoula River Basin tributaries are rated fair or poor due to pollution impacts (MDEQ 2014a, pp. 18–21; MDEQ 2008a, p. 17).

Nonpoint source pollution is a localized threat to the Pearl darter within the drainage, and is more prevalent in areas outside those lands protected by The Nature Conservancy and other areas managed by the State of Mississippi where Best Management Practices (BMPs) are utilized. Most water quality threats outside of protected lands are due to increased sediment loads and variations in pH (MDEQ 2014a, pp. 1–51; 2008a, pp. 13–15). Sediment in stormwater runoff increases water turbidity and temperature and originates locally from poorly maintained construction sites, timber harvest tracts, agricultural fields, clearing of riparian vegetation, and gravel extraction in the river floodplain. Excessive sediments disrupt feeding and spawning of fish and aquatic insects, abrade and suffocate periphyton (mixture of algae, bacteria, microbes, and detritus that is attached to submerged surfaces), and impact fish growth, survival, and reproduction (Waters 1995, pp. 55–62). A localized portion of the Chickasawhay River is on the State Section 303(d) List of Water Bodies as impaired due to sediment (MDEQ 2005b, p. 17).

Additionally, some contaminants may bind with one another within the Pascagoula River drainage (*i.e.,* heavy metals bind with sediments or other contaminants in the water column). These bound chemical contaminants have not been addressed in TMDLs. Only seven TMDLs for metals have been completed (MDEQ 2008a, pp. 1–55). The Davis Dead River, a tributary at the most downstream site of the Pearl darter's range, is considered critically impaired by mercury (MDEQ 2011, pp. 1–29), and fish consumption advisories continue for mercury in certain gamefish species in the Pascagoula River main stem (MDEQ 2008a, p. 43).

There are 15 permitted point source discharge sites within the Bouie River system (MDEQ 2005a, p. 6) and an unknown amount of nonpoint runoff sites. Municipal and industrial discharges during periods of low flow (*i.e.,* no or few rain events) intensify water quality degradation by increasing water temperatures, lowering dissolved oxygen, and changing pH. Within the Pascagoula River basin, pollutants causing specific channel or river reach impairment, (*i.e.,* those pollutants preventing the water body from reaching its applicable water quality standard (Environmental Protection Agency (EPA) 2012, pp. 1–9), include sedimentation (117 km (73 mi)); chemicals and nutrients in the water column (50 km (31 mi)); and various toxins, such as heavy metals like lead or cadmium (137 km (85 mi)). TMDLs were completed for pesticides such as DDT, toxaphene, dioxin, and pentachlorophenol, although much of the data and results are not finalized and remain unavailable for the designated reaches (EPA 2012, pp. 1–7; MDEQ 2003, pp. 5–10; Justus *et al.* 1999, p. 1; MDEQ 1994, pp. 1–13). No Pearl darters have been collected in the Bouie River (Bart *et al.* 2001, pp. 6–7) since 1997 (Ross *et al.* 2000, p. 3), though there is no specific data correlating the species' decline to the presence of these toxins.

Localized wastewater effluent into the Leaf River from the City of Hattiesburg is negatively impacting water quality (Hattiesburg American 2015, pp. 1–2; Mississippi River Collaboration 2014, p. 1; The Student Printz 2014, pp. 1–2). Existing housing, recreational cabins, and trailers along the banks of the Leaf River between I–59 to the town of Estabutchie add nutrient loading through sewage and septic water effluent (Mississippi River Collaboration 2014, p. 1). In 1997, Bart and Piller (p. 12) noted extensive algal growth during warmer months in the Leaf and Bouie Rivers, indicating nutrient and organic enrichment and decreases in dissolved oxygen and pH changes. Today, at specific locations, the water quality of the Bouie and Leaf Rivers continues to be negatively impacted by organic enrichment, low dissolved oxygen, fecal coliform and elevated nutrients (MDEQ 2005a, pp. 1–26; 2004, pp. 1–29).

Oil and Gas Development

Nonpoint and point source pollution from oil and gas exploration, including drill field construction, active drilling, and pipeline easements, may add localized pollutants into the Pascagoula River Basin during stormwater runoff events if BMPs are not used. There is one major oil refinery within the basin along with 6 oil pumping stations, 10 major crude pipelines, 4 major product oil pipelines, and 5 major gas and more than 25 lesser gas lines stretching hundreds of miles and crisscrossing the main stem Pascagoula, Bouie, Leaf, and Chickasawhay Rivers and tributaries; in addition, there are more than 100 active oil producing wells within the Pearl darters' watersheds (compiled from Oil and Gas map of Mississippi in Phillips 2013, pp. 10, 23). All have the potential to rupture and/or leak and cause environmental and organismal damage as evidenced by the Genesis Oil Co. and Leaf River oil spill of 2000 (Environmental Science Services, Inc. 2000, pp. 1–50; Kemp Associates, PA, 2000, pp. 4–5; The Clarion-Ledger, December 23, 1999, p. 1B) and Genesis Oil spill in Okatoma Creek in February 2016 (Drennen pers. observ. 2016). In addition to gas pipelines, there are numerous railways that cross Pearl darter habitat that are subject to accidental and catastrophic spilling of toxins such as fuel oil, methanol, resin, and fertilizer (MDEQ 2014b, pp. 1–23).

Alternative oil and gas collection methods (*i.e.,* hydraulic fracturing ("fracking") and horizontal drilling and injection) have allowed for the expansion of oil and gas drilling into deposits that were previously inaccessible (Phillips 2013, p. 21), which has led to increased activity within southern Mississippi, including portions of the Pascagoula River Basin. There are more than 100 water injection disposal wells and enhanced oil recovery wells within the Basin (compiled from Active Injection Well Map of Mississippi in Phillips 2013, p. 49). A variety of chemicals (*e.g.,* hydrochloric acid, surfactants, potassium chloride) are used during the drilling and fracking process (Colborn *et al.* 2011, pp. 1040–1042), and their wastes are stored in open pits (retention basins) or storage facilities. Spills during transport or releases due to retention basin failure or overflow pose a risk for surface and groundwater contamination, which can cause significant adverse effects to water quality and aquatic organisms that inhabit these watersheds (Osborn *et al.* 2011, pp. 8172–8176; Kargbo *et al.* 2010, pp. 5680–5681; Wiseman 2009, pp. 127–142). There is currently no routine water quality monitoring in areas where the Pearl darter currently occurs, so it is unlikely that the effects of a leak or spill would be detected quickly to allow for a timely response.

Geomorphology Changes

Pearl darters are not found in impounded waters and are intolerant of lentic (standing water) habitats that may be formed by gravel mining or other landscape-altering practices. The results of historical sand and gravel dredging impacts have been a concern for the Bouie and Leaf Rivers (MDEQ 2000, pp. 1–98). Historically, the American Sand and Gravel Company (ASGC) (1995, p. B4) has mined sand and gravel using a hydraulic suction dredge, operating within the banks or adjacent to the Bouie and Leaf Rivers. Large gravel bars of the river and its floodplain have been removed over the past 50 years, creating open-water areas that function as deep lake systems (ASGC 1995, pp. B4–B8). The creation of these large, open-water areas has accelerated geomorphic processes, specifically headcutting (erosional feature causing an abrupt drop in the streambed), that has adversely affected the flora and fauna of many coastal plain streams (Patrick *et al.* 1993, p. 90). Mining in active river channels typically results in incision upstream of the mine by knickpoints (break in the slope of a river or stream profile caused by renewed erosion attributed to a bottom disturbance that may retreat upstream), sediment deposition downstream, and an alteration in channel morphology that can have impacts for years (Mossa and Coley 2004, pp. 1–20). The upstream migration of knickpoints, or headcutting, may cause undermining of structures, lowering of alluvial water tables (aquifer comprising unconsolidated materials deposited by water and typically adjacent to rivers), channel destabilization and widening, and loss of aquatic and riparian habitat. This geomorphic change may cause the extirpation of riparian and lotic (flowing water) species (Patrick *et al.* 1993, p. 96). Lyttle (1993, p. 70) and Brown and Lyttle (1992, pp. 2, 46) found that instream gravel mining reduces overall fish species diversity in Ozark streams and favors a large number of a few small fish species, such as the Central stoneroller (*Campostoma anomalum*) and most darters (*Etheostoma* sp.).

The decline of the Pearl darter in the Bouie River and Black Creek may be from sedimentation caused by unstable banks and loose and unconsolidated streambeds (Bart and Piller 1997, p. 12). Mossa and Coley (2004, p. 17) determined that, of the major tributaries in the Pascagoula basin, the Bouie River was the least stable. Channel enlargement of the Bouie River showed higher than background values associated with avulsions (the rapid abandonment of a river channel and the formation of a new river channel) into floodplain pits and increased sedimentation. In addition, channel enlargement of 400 to 500 percent in the Bouie River has occurred at specific sites due to instream gravel mining (Mossa *et al.* 2006, entire; Mossa and Coley 2004, p. 17). Ayers (2014, pp. 43–45) also found significant and lengthy instream channel form changes in the Chickasawhay River floodplain. Clark and Schaefer (2015, pp. 13–14) noted a slight decrease in fish species richness in the upper Pascagoula River basin from their 2004 sampling, which they attributed to past anthropogenic influences such as gravel mining, bankside practices, and construction.

In the Bogue Chitto River of the Pearl River basin, Stewart *et al.* (2005, pp. 268–270) found that the assemblages of fishes had shifted over 27 years. In this time period, the sedimentation rates within the system had increased dramatically and caused the decrease in the relative abundance of all fish in the family Percidae (Stewart *et al.* 2005, pp. 268–270) from 35 percent to 9 percent, including the extirpation of Pearl darters. Ross *et al.* (1992, pp. 8–9) studied threats to the Okatoma Creek (Pascagoula Basin) fish diversity and predicted that geomorphic changes to the stream would reduce the fish habitat diversity resulting in a decline of the fish assemblages, including the rare Pearl darter.

Impoundments

The proposed damming of Little and Big Cedar Creeks, tributaries to the Pascagoula River, for establishment of two recreational lakes (George County Lakes) (U.S. Army Corps of Engineers 2015, pp. 1–13) has prompted the American Rivers organization to recently list the Pascagoula River as the 10th most endangered river in the country (American Rivers 2016, pp. 20–21). Though the proposed project is not directly within known Pearl darter habitat, the lakes will decrease water quantity entering the lower Pascagoula Basin, and will likely concentrate pollutants, reduce water flow, and alter downstream food webs and aquatic productivity (Poff and Hart 2002, p. 660).

Summary of Factor A

Habitat modification and resultant water quality degradation are occurring within the Pearl darter's current range. Increased sedimentation from the removal of riparian vegetation and extensive cultivation is thought to have led to the extirpation of the Pearl darter from the Pearl River drainage. Water quality degradation occurs locally from point and nonpoint source pollution in association with land surface, stormwater, and effluent runoff from urbanization and municipal areas. Increased sediment from a variety of sources, including geomorphological changes and bank instability from past habitat modification, appears to be the major contributor to water quality declines in this species' habitat. Localized sewage and waste water effluent also pose a threat to this species and its habitat. The Pearl darter's vulnerability to catastrophic events, particularly the release of pollutants in its habitat from oil spills, train derailments, and hydraulic fracturing, is also a concern due to the abundance of oil wells, pumping stations, gas lines, and railways throughout its habitat, and the increased interest in alternative oil and gas collection methods in the area. The proposed damming of Big and Little Cypress creeks may decrease water flow and increase nutrients and sedimentation into the Pascagoula River. These threats continue to impact water quality and habitat conditions through much of this species' current range. Therefore, we conclude that habitat degradation is presently a moderate threat to the Pearl darter that is expected to continue and possibly increase into the future.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

In general, Pearl darters are unknown to the public and are not used for either sport or bait purposes. Therefore, collection of this species by the public is not currently identified as a threat. Scientific collecting is controlled by the State through permits; thus, scientific collecting and take by private and institutional collectors are not presently identified as threats. Therefore, overutilization for commercial, recreational, scientific, or educational purposes does not pose a threat to the Pearl darter now or in the future.

Factor C: Disease or Predation

Predation on the Pearl darter by other fish, reptiles, and other organisms undoubtedly occurs; however, there is no evidence to suggest that any predators threaten this species. There is also no evidence that disease is a threat. Therefore, neither disease nor predation poses a threat to the Pearl darter now or in the future.

Factor D: The Inadequacy of Existing Regulatory Mechanisms

The State of Mississippi classifies the Pearl darter as endangered in the State (Mississippi Natural Heritage Program 2015, p. 2), and prohibits the collection of the Pearl darter for scientific purposes without a State-issued collecting permit. However, as discussed under Factor B, we have no evidence to suggest that scientific collection poses a threat to this species. This State endangered designation conveys no legal protection for the Pearl darter's habitat nor prohibits habitat degradation, which is the primary threat to the species. The Pearl darter receives no protection in Louisiana, where it is considered historic in the State (Louisiana Department of Wildlife and Fisheries 2016, p. 5).

The Pearl darter and its habitats are afforded some protection from water quality and habitat degradation under the Clean Water Act of 1972 (33 U.S.C. 1251 *et seq.*) and the Mississippi Water Pollution Control Law, as amended, 1993 (Code of Mississippi, §§ 49–17–1, *et seq.*) and regulations promulgated thereunder by the Mississippi Commission on Environmental Quality. Although these laws have resulted in some temporary enhancement in water quality and habitat for aquatic life, they have been inadequate in fully protecting the Pearl darter from sedimentation and other nonpoint source pollutants.

The State of Mississippi maintains water-use classifications through issuance of National Pollutant Discharge Elimination System permits to industries, municipalities, and others that set maximum limits on certain pollutants or pollutant parameters. For water bodies on the Clean Water Act section 303(d) list, the State is required to establish a TMDL for the pollutants of concern that will improve water quality to the applicable standard. The establishment of TMDLs for 89 river or stream segments and ratings of fair to poor for 39 percent of the tributaries within the Pascagoula basin are indicative of pollution impacts within the Pearl darter's habitat (MDEQ 2008a,

p. 17). TMDLs are not an enforced regulation, and only reflect benchmarks for improving water quality; they have not been successful in reducing water quality degradation within this species' habitat.

Mississippi Surface Mining and Reclamation Law, Miss. Code Ann. § 53–7–1 *et seq.*, and Federal laws regarding oil and gas drilling (42 U.S.C. 6921) are generally designed to protect freshwater resources like the Pearl darter, but these regulatory mechanisms do not contain specific provisions requiring an analysis of project impacts to fish and wildlife resources. They also do not contain or provide for any formal mechanism requiring coordination with, or input from, the Service or the Mississippi Department of Wildlife, Fisheries and Parks regarding the presence of federally endangered, threatened, or candidate species, or other rare and sensitive species. In the case of surface mining, penalties may be assessed if damage is serious, but there is no immediate response for remediation of habitats or species. As demonstrated under Factor A, periodic declines in water quality and degradation of habitat for this species are ongoing despite these protective regulations. These mechanisms have been inadequate to protect the species from sediment runoff and turbidity within its habitat associated with land surface runoff and municipal/industrial discharges, as described under Factor A. There are currently no requirements within the scope of other statewide environmental laws to specifically consider the Pearl darter or ensure that a project will not significantly impact the species.

The Pearl darter likely receives ancillary protection (*i.e.,* water quality improvements, protection from geomorphological changes) where it co-occurs with two other federally listed species, the Gulf sturgeon (*Acipenser oxyrhynchus desotoi*) and yellow blotched map turtle (*Graptemys flavimaculata*), during the course of consultation on these species under section 7 of the Act. However, protective measures through section 7 of the Act would only be triggered for those projects having a Federal nexus, which would not address many of the water quality disturbances caused by industry, municipalities, agriculture, or private landowners.

Additional ancillary protection of 53,520 hectares (ha) (132,128 acres (ac)) within the Pascagoula basin watershed occurs due to the Mississippi Wildlife, Fisheries and Parks' management of six Wildlife Management Areas (WMAs) within the drainage for recreational hunting and fishing. Point and nonpoint sediment sources are decreased or reduced by using and monitoring BMP's during silviculture, road maintenance, and other landscape-altering methods. Four of the six WMAs (Chickasawhay and Leaf Rivers, Mason and Red Creeks) do not directly border the river system, but they do contain and protect parcels of upland buffer, wetland, and tributaries to the basin. The Pascagoula River and Ward Bayou WMAs include 20,329 ha (50,234 ac) consisting of mainly wetland buffer and river/stream reach of the basin within the current range of the Pearl darter, protecting approximately 106 km (66 mi) of the Pascagoula River main stem (Stowe, pers. comm., 2015). The Nature Conservancy (TNC) protects 14,164 ha (35,000 ac) within the Pascagoula River watershed and approximately 10 km (6 mi) of the Pascagoula River shoreline in Jackson County, Mississippi. Of that amount, the Charles M. Deaton Nature Preserve (1,336 ha, 3,300 ac) protects the headwaters of the Pascagoula River, where the Leaf and Chickasawhay Rivers converge, and is part of a 19,020-ha (47,000-ac) swath of public lands surrounding the Pascagoula River, which includes approximately 8 km (5 mi) of the Chickasawhay River and approximately 7 km (4 mi) of the Leaf River shorelines (Becky Stowe 2015, pers. comm.).

These State-managed WMAs and TNC preserves provide a measure of protection for approximately 134 km (84 mi) or 30 percent of the river reaches within this species' current range. Even though 116 of these 134 km (72 of 84 mi) are located within the Pascagoula River mainstem, only short segments of shoreline are protected in the Chickasawhay and Leaf Rivers. The remaining segments, not within WMA's and TNC preserves, are vulnerable to farming and timbering to the bankside edge, and construction of structures such as houses, septic facilities, dams, and ponds. Each land management action increases stormwater runoff laden with sediment and agricultural and wastewater chemicals.

Summary of Factor D

Outside of the areas protected or managed by the State and TNC, and despite existing authorities, such as the Clean Water Act, pollutants continue to impair the water quality throughout much of the current range of the Pearl darter. State and Federal regulatory mechanisms have helped reduce the negative effects of point source and nonpoint source discharges, yet there is inconsistency in the implementation of these regulations and BMPs, which are not mandatory for all activities. Thus, we conclude that existing regulatory mechanisms do not adequately protect the Pearl darter from the impact of other threats.

Factor E: Other Natural or Manmade Factors Affecting Its Continued Existence

Small Population Size and Loss of Genetic Diversity

The Pearl darter is included on the Southeastern Fishes Council list of the 12 most imperiled species (Kuhajda *et al.* 2009, pp. 17–18). This species has always been considered rare (Deacon *et al.* 1979, p. 42) and is currently restricted to localized sites within the Pascagoula River drainage. Genetic diversity has likely declined due to fragmentation and separation of reproducing Pearl darter populations. Kreiser *et al.* (2012, p. 12) found that disjunct populations of Pearl darters within the Leaf and Chickasawhay Rivers showed some distinct alleles suggesting that gene flow between the two rivers was restricted and perhaps that the total gene pool diversity was declining.

Species that are restricted in range and population size are more likely to suffer loss of genetic diversity due to genetic drift, potentially increasing their susceptibility to inbreeding depression, decreasing their ability to adapt to environmental changes, and reducing the fitness of individuals (Allendorf and Luikart 2007, pp. 117–146; Soulé 1980, pp. 157–158). It is likely that some of the Pearl darter populations are below the effective population size required to maintain long-term genetic and population viability (Soulé 1980, pp. 162–164). Collecting data (Ross 2001, p. 500; Bart and Piller 1997, p. 4; Bart and Suttkus 1996, p. 4; Suttkus *et al.* 1994, p. 19) indicate that the Pearl darter is rare in the Pascagoula River system, as when this species is collected it is typically in low numbers and a disproportionately low percentage of the total fish collected.

In addition, preliminary information indicates that there may be low genetic diversity within the Pearl darter populations, especially among populations within the Leaf and Chickasawhay Rivers where it appears gene flow between the two rivers may be restricted (Kreiser *et al.* 2013, pp. 14–17). The long-term viability of a species is founded on the conservation of numerous local populations throughout its geographic range (Harris 1984, pp. 93–104). The presence of viable, separate populations is essential for a species to recover and adapt to environmental change (Noss and Cooperrider 1994, pp. 264–297; Harris 1984, pp. 93–104). Inbreeding and loss of neutral genetic variation associated with small population size reduce the fitness of the population (Reed and Frankham 2003, pp. 230–237) and accelerate population decline (Fagan and Holmes 2006, pp. 51–60). The species' small numbers within scattered locations coupled with its lack of genetic variability may decrease the species' ability to adapt or recover from major hydrological events that impact potential spawning habitat (Clark and Schaeffer 2015, pp. 18–22).

Hurricanes

Fish and aquatic communities and habitat, including that of the Pearl darter, may be changed by hurricane influences (Schaefer *et al.* 2006, pp. 62–68). In 2005, Hurricane Katrina destroyed much of the urban and industrial areas along the lower Pascagoula River basin and also impacted the ecology upriver to the confluence with the Leaf and Chickasawhay Rivers. Many toxic chemicals that leaked from grounded and displaced boats and ships, storage facilities, vehicles, septic systems, business sites, and other sources were reported in the rivers, along with saltwater intrusion from the Gulf of Mexico. Initial assessment identified several fish kills and increased surge of organic material into the waters, which lowered dissolved oxygen levels (Schaefer *et al.* 2006, pp. 62–68).

Climate Change

The Intergovernmental Panel on Climate Change (IPCC) concluded that warming of the climate system is unequivocal (IPCC 2014, p. 3). Numerous long-term climate changes have been observed including changes in arctic temperatures and ice, widespread changes in precipitation amounts, ocean salinity, wind patterns, and aspects of extreme weather including droughts, heavy precipitation, heat waves, and the intensity of tropical cyclones (IPCC 2014, p. 4). Species that are dependent on specialized habitat types, limited in distribution, or at the extreme periphery of their range may be most susceptible to the impacts of climate change (see 75 FR 48911, August 12, 2010); however, while continued change is certain, the magnitude and rate of change is unknown in many cases.

Climate change has the potential to increase the vulnerability of the Pearl darter to random catastrophic events (Thomas *et al.* 2004, pp. 145–148; McLaughlin *et al.* 2002, pp. 6060–6074). An increase in both severity and variation in climate patterns is expected, with extreme floods, strong storms, and droughts becoming more common (IPCC 2014, pp. 58–83). Thomas *et al.* (2004, pp. 145–148) report that frequency, duration, and intensity of droughts are likely to increase in the Southeast as a result of global climate change. Kaushal *et al.* (2010, p. 465) reported that stream temperatures in the Southeast have increased roughly 0.2–0.4 °C (0.3–0.7 °F) per decade over the past 30 years, and as air temperature is a strong predictor of water temperature, stream temperatures are expected to continue to rise. Predicted impacts of climate change on fishes, related to drought, include disruption to their physiology (*e.g.,* temperature tolerance, dissolved oxygen needs, and metabolic rates), life history (*e.g.,* timing of reproduction, growth rate), and distribution (*e.g.,* range shifts, migration of new predators) (Comte *et al.* 2013, pp. 627–636; Strayer and Dudgeon 2010, pp. 350–351; Heino *et al.* 2009, pp. 41–51; Jackson and Mandrak 2002, pp. 89–98). However, estimates of the effects of climate change using available climate models typically lack the geographic precision needed to predict the magnitude of effects at a scale small enough to discretely apply to the range of a given species. Therefore, there is uncertainty about the specific effects of climate change (and their magnitude) on the Pearl darter; however, climate change is almost certain to affect aquatic habitats in the Pascagoula River basin through increased water temperatures and more frequent droughts (Alder and Hostetler 2013, pp. 1–12), and species with limited ranges, fragmented distributions, and small population size are thought to be especially vulnerable to the effects of climate change (Byers and Norris 2011, p. 18). Thus, we consider climate change to be a threat to the Pearl darter.

Summary of Factor E

Because the Pearl darter has a limited geographic range, small population numbers, and low genetic diversity, it is vulnerable to several other ongoing natural and manmade threats. These threats include the loss of genetic fitness, susceptibility to spills and other catastrophic events, and impacts from climate change. These threats are current and are likely to continue or increase in the future.

Cumulative Effects of Factors A Through E

The threats that affect the Pearl darter are important on a threat-by-threat basis but are even more significant in combination. Due to the loss of the species from the Pearl River system, the Pearl darter is now confined to a single drainage system. The species is continuing to experience water quality degradation from point and nonpoint source pollution in association with land-altering activities, discharges from municipalities, and geomorphological changes from past gravel mining. The laws and regulations directed at preventing water quality degradation have been ineffective at providing for the conservation of the Pearl darter. Furthermore, these threats and their effect on this species are exacerbated due to the Pearl darter's small population numbers and low genetic diversity, which reduce its genetic fitness and resilience to possible catastrophic events. Though projecting possible synergistic effects of climate change on the Pearl darter is somewhat speculative, climate change and its effects of increased water temperatures and more frequent droughts will have a greater negative impact on species with limited ranges and small population sizes, such as the Pearl darter. While these threats or stressors may act in isolation, it is more probable that many stressors are acting simultaneously (or in combination) on the Pearl darter.

Proposed Determination

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Pearl darter. As described in detail above, the Pearl darter has been extirpated from about 57 percent of its historical range and it is now confined to the Pascagoula River watershed. The species occurs in low numbers within its current range, and continues to be at risk throughout all of its range due to the immediacy, severity, and scope of threats from habitat degradation and range curtailment (Factor A) and other natural or manmade factors affecting its continued existence (Factor E). Existing regulatory mechanisms have been inadequate in ameliorating these threats (Factor D).

Anthropogenic activities such as land development, agriculture, silviculture, oil and gas development, inadequate sewage treatment, stormwater runoff, past gravel mining and resultant geomorphological changes, and construction of dams or sills, have all contributed to the degradation of stream habitats and particularly water quality within this species' range (Factor A). These land use activities have led to chemical and physical changes in the mainstem rivers and tributaries that continue to affect the species through negative impacts to its habitat. Specific threats include inputs of sediments, siltation of stream substrates, turbidity, and inputs of dissolved solids. These threats, especially the inputs of dissolved solids and sedimentation, have had profound negative effects on Pearl darter populations and have been the primary factor in the species' decline. Existing regulatory mechanisms (*e.g.*, the Clean Water Act) have provided for some improvements in water quality and habitat conditions across the species' range, but these laws and regulations have been inadequate in protecting the species' habitat (Factor D), as evidenced by the extirpation of the species within the Pearl River basin and the number of section 303(d) listed streams within the species' historical range. The Pearl darter's vulnerability to these threats is even greater due to its reduced range, fragmented populations, small population sizes, and low genetic diversity (Factor E). The effects of certain threats, particularly habitat degradation and loss, increase in magnitude when population size is small (Primack 2012, pp. 150–152).

The Act defines an endangered species as any species that is "in danger of extinction throughout all or a significant portion of its range" and a threatened species as any species "that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future." We find that the Pearl darter is likely to become endangered throughout all or a significant portion of its range within the foreseeable future, based on the immediacy, severity, and scope of the threats currently impacting the species. The overall range has been reduced substantially and the remaining habitat and populations are threatened by a variety of factors acting in combination to reduce the overall viability of the species over time. The risk of becoming endangered is high because populations are confined to a single watershed, most are small in size, and numerous threats are impacting them. However, we find that endangered species status is not appropriate. Despite low population numbers and numerous threats, populations in the Chickasawhay and Leaf Rivers, which are the largest, appear to be stable and reproducing. In addition, the magnitude of threats is considered to be moderate overall, since the threats are having a localized impact on the species and its habitat. For example, water quality degradation, the most prevalent threat, is not as pervasive within areas protected with BMPs, and geomorphic changes, caused by past sand and gravel mining, are also sporadic within its habitat. Therefore, on the basis of the best available scientific and commercial information, we propose listing the Pearl darter as threatened in accordance with sections 3(6) and 4(a)(1) of the Act.

Under the Act and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. Because we have determined that Pearl darter is threatened throughout all of its range, no portion of its range can be "significant" for purposes of the definitions of "endangered species" and "threatened species." See the Final Policy on Interpretation of the Phrase "Significant Portion of Its Range" in the Endangered Species Act's Definitions of "Endangered Species" and "Threatened Species" (79 FR 37577, July 1, 2014).

Critical Habitat

Section 3(5)(A) of the Act defines critical habitat as "(i) the specific areas within the geographical area occupied by the species, at the time it is listed . . . on which are found those physical or biological features (I) Essential to the conservation of the species and (II) which may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed . . . upon a determination by the Secretary that such areas are essential for the conservation of the species."

Section 4(a)(3) of the Act and implementing regulations (50 CFR 424.12) require that we designate critical habitat at the time a species is determined to be an endangered or threatened species, to the maximum extent prudent and determinable. Our regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist: (1) The species is threatened by taking or other activity and the identification of critical habitat can be expected to increase the degree of threat to the species; or (2) such designation of critical habitat would not be beneficial to the species. There is currently no imminent threat of take attributed to collection or vandalism under Factor B for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In the absence of finding that the designation of critical habitat would increase threats to a species, if there are any benefits to a critical habitat designation, a finding that designation is prudent is warranted. Here, the potential benefits of designation include: (1) Triggering consultation under section 7 of the Act, in new areas for action in which there may be a Federal nexus where it would not otherwise occur because, for example, it is unoccupied; (2) focusing conservation activities on the most essential features and areas; (3) providing educational benefits to State or county governments or private entities; and (4) preventing inadvertent harm to the species. Accordingly, because we have determined that the designation of critical habitat will not likely increase the degree of threat to the species and may provide some measure of benefit, we determine that designation of critical habitat is prudent for the Pearl darter.

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the species is determinable. Our regulations (50 CFR 424.12(a)(2)) further state that critical habitat is not determinable when one or both of the following situations exist: (i) Information sufficient to perform required analysis of the impacts of the designation is lacking; or (ii) The biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

As discussed above, we have reviewed the available information pertaining to the biological needs of the species and habitat characteristics where the species is located. On the basis of a review of available information, we find that critical habitat for the Pearl darter is not determinable because the specific information sufficient to perform the required analysis of the impacts of the designation is currently lacking, such as information on areas to be proposed for designation and the potential economic impacts associated with designation of these areas. We are in the process of obtaining this information. We will make a determination on critical habitat no later than 1 year following any final listing determination.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for downlisting or delisting, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. If the species is listed, the recovery outline, draft recovery plan, and the final recovery plan would be available on our Web site (*http://www.fws.gov/endangered*), or from our Mississippi Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands. If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of Mississippi would be eligible for Federal funds to implement management actions that promote the protection or recovery of the Pearl darter. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the Pearl darter is only proposed for listing under the Act at this time, please let us know if you are interested in participating in conservation efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the U.S. Forest Service; issuance of section 404 Clean Water Act permits by the U.S. Army Corps of Engineers; construction and maintenance of gas and oil pipelines and power line rights-of-way by the Federal Energy Regulatory Commission; Environmental Protection Agency pesticide registration; and construction and maintenance of roads or highways by the Federal Highway Administration.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to threatened wildlife. The prohibitions of section 9(a)(1) of the Act, as applied to threatened wildlife and codified at 50 CFR 17.31, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) threatened wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any listed species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. Based on the best available information, the following actions are unlikely to result in a violation of section 9, if these activities are carried out in accordance with existing regulations and permit requirements; this list is not comprehensive:

(1) Normal agricultural and silvicultural practices, including

herbicide and pesticide use, which are carried out in accordance with existing regulations, permit and label requirements, and best management practices.

(2) Normal residential and urban landscape activities, such as mowing, edging, fertilizing, etc.

(3) Normal pipeline/transmission line easement maintenance.

(4) Normal bridge, culvert, and roadside maintenance consistent with appropriate best management practices for these activities.

Based on the best available information, the following activities may potentially result in a violation of section 9 of the Act; this list is not comprehensive:

(1) Unauthorized handling or collecting of the species.

(2) Introduction of nonnative fish that compete with or prey upon the Pearl darter.

(3) Discharge or dumping of toxic chemicals, contaminants, sediments, waste water effluent, or other pollutants into waters supporting the Pearl darter that kills or injures individuals, or otherwise impairs essential life-sustaining behaviors such as spawning, feeding, or sheltering.

(4) Destruction or alteration of the species' habitat (*e.g.,* unpermitted instream dredging, impoundment, water diversion or withdrawal, channelization, discharge of fill material, modification of tributaries, channels, or banks) that impairs essential behaviors such as spawning, feeding, or sheltering, or results in killing or injuring a Pearl darter.

(5) Mining, oil and gas processes, silviculture, and agricultural processes that result in direct or indirect destruction of riparian bankside habitat or in channel habitat in waters supporting the Pearl darter that kills or injures individuals, or otherwise impairs essential life-sustaining behaviors such as spawning, feeding, or sheltering.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Mississippi Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes. There are no tribal lands located within the range of this species.

References Cited

A complete list of references cited in this proposed rulemaking is available on the Internet at *http://www.regulations.gov* and upon request from the Mississippi Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Mississippi Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245; unless otherwise noted.

■ 2. In § 17.11(h), add an entry for "Darter, Pearl" to the List of Endangered and Threatened Wildlife in alphabetical order under FISHES to read as set forth below:

§ 17.11 Endangered and threatened wildlife.

* * * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
FISHES				

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	* * *
Darter, Pearl	*Percina aurora*	Wherever found	T	[**Federal Register** citation when published as a final rule].
*	*	*	*	* * *

Dated: August 30, 2016.

James W. Kurth,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2016–22752 Filed 9–20–16; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 81, No. 183
Wednesday, September 21, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Rio Grande National Forest; Colorado; Revision of the Land Management Plan for the Rio Grande National Forest; Correction

AGENCY: Forest Service, USDA.

ACTION: Notice of intent; correction.

SUMMARY: The USDA Forest Service published a notice of intent to prepare an environmental impact statement in the **Federal Register** of September 12, 2016. The document contains confusing language regarding establishing standing for participation in the agency's admininstrative review process.

FOR FURTHER INFORMATION CONTACT: Erin Minks, Plan Revision Team Leader, *eminks@fs.fed.us,* 719–852–6215. Information on plan revision is also available at *www.fs.usda.gov/riogrande.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m. Eastern Time, Monday through Friday.

Correction

In the **Federal Register** of September 12, 2016 (81 FR 176), on page 62706, in the third column in the **DATES** section, correct the section to read:

DATES: Comments concerning the scope of the analysis will be accepted throughout the entire plan revision process. Members of the public who wish to establish standing to participate in the objection process must submit substantive formal comments on the plan revision during one of the opportunities to comment in accordance with 36 CFR 219 subpart B. This scoping period, which ends 45 days from the publication of the Legal Notice in the Valley Courier, is one of the formal periods that can establish standing to object.

Dated: September 13, 2016.

Dan Dallas,

Forest Supervisor, Rio Grande National Forest.

[FR Doc. 2016–22706 Filed 9–20–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Publication of Depreciation Rates

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of depreciation rates for telecommunications plant.

SUMMARY: The United States Department of Agriculture (USDA) Rural Utilities Service (RUS) administers rural utilities programs, including the Telecommunications Program. RUS announces the depreciation rates for telecommunications plant for the period ending December 31, 2015.

DATES: These rates are effective immediately and will remain in effect until rates are available for the period ending December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Keith B. Adams, Assistant Administrator, Telecommunications Program, Rural Utilities Service, STOP 1590—Room 5151, 1400 Independence Avenue SW., Washington, DC 20250–1590. Telephone: (202) 720–9556.

SUPPLEMENTARY INFORMATION: In 7 CFR part 1737, Pre-Loan Policies and Procedures Common to Insured and Guaranteed Telecommunications Loans, § 1737.70(e) explains the depreciation rates that are used by RUS in its feasibility studies. Section 1737.70(e)(2) refers to median depreciation rates published by RUS for all borrowers. The following chart provides those rates, compiled by RUS, for the reporting period ending December 31, 2015:

MEDIAN DEPRECIATION RATES OF RURAL UTILITIES SERVICE BORROWERS BY EQUIPMENT CATEGORY FOR PERIOD ENDING DECEMBER 31, 2015

Telecommunications plant category	Depreciation rate
1. Land and Support Assets:	
a. Motor vehicles	16.00
b. Aircraft	11.25
c. Special purpose vehicles	12.00
d. Garage and other work equipment	10.00
e. Buildings	3.30
f. Furniture and office equipment	10.00
g. General purpose computers	20.00
2. Central Office Switching:	
a. Digital	9.70
b. Analog & Electro-mechanical	10.00
c. Operator Systems	9.90
3. Central Office Transmission:	
a. Radio Systems	10.00
b. Circuit equipment	10.00
4. Information origination/termination:	
a. Station apparatus	12.00
b. Customer premises wiring	10.65
c. Large private branch exchanges	10.96
d. Public telephone terminal equipment	12.00
e. Other terminal equipment	10.35
5. Cable and wire facilities:	
a. Aerial cable—poles	6.42
b. Aerial cable—metal	5.90
c. Aerial cable—fiber	5.00
d. Underground cable—metal	5.00
e. Underground cable—fiber	5.00
f. Buried cable—metal	5.15
g. Buried cable—fiber	5.00
h. Conduit systems	3.93
i. Other	5.00

Dated: September 13, 2016.

Brandon McBride,

Administrator, Rural Utilities Service.

[FR Doc. 2016–22747 Filed 9–20–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Notice and opportunity for public comment.

Pursuant to Section 251 of the Trade Act 1974, as amended (19 U.S.C. 2341 *et seq.*), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of these firms contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[9/8/2016 through 9/14/2016]

Firm name	Firm address	Date accepted for investigation	Product(s)
T.D.R.N, Inc	16187 North Balsam Lane, Spalding, MI 49886.	9/13/2016	The firm manufactures precision machined metal components, such as studs, collars and spacers.
Mayco Industries, LLC	18 West Oxmoor Road, Birmingham, AL 36271.	9/14/2016	The firm manufactures lead-based products such as lead shots, antimonial and custom alloys.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance for Firms Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Miriam Kearse,

Lead Program Analyst.

[FR Doc. 2016–22638 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–62–2016]

Foreign-Trade Zone (FTZ) 20—Newport News, Virginia, Notification of Proposed Production Activity, Canon Virginia, Inc., Subzone 20D (Toner Cartridges), Newport News, Virginia

Canon Virginia, Inc. (Canon), operator of Subzone 20D, submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 20D, in Newport News, Virginia. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on September 2, 2016.

Canon already has authority to produce a range of printers, copiers and their parts and supplies, including toner, toner cartridges, toner bottles and cartridge parts, within Subzone 20D. The current request would add foreign status materials/components to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials/components described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Canon from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, Canon would be able to choose the duty rate during customs entry procedures that applies to toner cartridges (duty free) for the foreign-status materials/components noted below and in the existing scope of authority. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The materials/components sourced from abroad include: Paints and varnishes; plastic sheets/bottles/cases/crates; paper labels; iron or steel screws; and, alloyed aluminum tubes (duty rates range from free to 8.6%).

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is October 31, 2016.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: September 15, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–22767 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–61–2016]

Foreign-Trade Zone (FTZ) 79—Tampa, Florida, Notification of Proposed Production Activity, Givaudan Flavors Corporation (Flavor Compounds), Lakeland, Florida

Givaudan Flavors Corporation (Givaudan) submitted a notification of proposed production activity to the FTZ Board for its facility in Lakeland, Florida within FTZ 79. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on September 12, 2016.

The Givaudan facility is used for the production of flavor compounds. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Givaudan from customs duty payments on the foreign status components used in export production. On its domestic sales, Givaudan would be able to choose the duty rates during customs entry procedures that apply to cocoa food preparations, dairy food preparations, coffee food preparations, seasonings, sauces, alcoholic preparations for beverages, other food preparations with dairy, confectionary preparations without sugar, other food preparations, food articles containing sugar, other cyclanes, cyclenes and cycloterpenes, other cyclic hydrocarbons, acyclic terpene alcohols, butanoic acids, pentanoic acids, their salts and esters, concentrated orange oil, concentrated lemon oil, citrus oil blends, aqueous distillates and aqueous solutions of essential oils, terpenic by-products of the deterpenation of essential oils, flavor preparations for food or drink without alcohol, flavor preparations for food or drink with alcohol, odoriferous substances other than food or drink or perfume bases with alcohol, odiferous substances other than food or drink or perfume bases without alcohol (duty rate ranges from free to 70.4c/kg + 8.5%) for the foreign status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign status production equipment.

The materials sourced from abroad include benzaldehyde, vanillin, orange oil, concentrated orange oil, lemon oil, and concentrated lemon oil (duty rate ranges from 2.7% to 5.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is October 31, 2016.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz*.

For further information, contact Kathleen Boyce at *Kathleen.Boyce@trade.gov* or (202) 482–1346.

Dated: September 15, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–22769 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Denying Export Privileges

In the Matter of: Francisco Javier Mendoza-Esquivel, Register Number: 62841–179, Federal Correctional Institution, 2001 Rickabaugh Drive, Big Spring, TX 79720.

On August 11, 2015, in the U.S. District Court for the Southern District of Texas, Francisco Javier Mendoza-Esquivel ("Mendoza-Esquivel"), was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) ("AECA"). Specifically, Mendoza-Esquivel intentionally and knowingly conspired and agreed to knowingly and willfully export, attempt to export, and cause to be exported into Mexico from the United States a defense article, that is, to wit: Approximately five thousand eight hundred and sixty (5,860) rounds of 7.62 x 39 mm caliber ammunition which were designated as defense articles on the United States Munitions List, without having first obtained from the Department of State a license for such export or written authorization for such export. Mendoza-Esquivel was sentenced 51 months of imprisonment and a $100 assessment.

Section 766.25 of the Export Administration Regulations ("EAR" or "Regulations")[1] provides, in pertinent part, that "[t]he Director of the Office of Exporter Services, in consultation with the Director of the Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of the Export Administration Act ("EAA"), the EAR, or any order, license or authorization issued thereunder; any regulation, license, or order issued under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706); 18 U.S.C. 793, 794 or 798; section 4(b) of the Internal Security Act of 1950 (50 U.S.C. 783(b)), or section 38 of the Arms Export Control Act (22 U.S.C. 2778)." 15 CFR 766.25(a); *see also* Section 11(h) of the EAA, 50 U.S.C. 4610(h). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d); *see also* 50 U.S.C. 4610(h). In addition, Section 750.8 of the Regulations states that the Bureau of Industry and Security's Office of Exporter Services may revoke any Bureau of Industry and Security ("BIS") licenses previously issued in which the person had an interest in at the time of his conviction.

BIS has received notice of Mendoza-Esquivel's conviction for violating the AECA, and has provided notice and an opportunity for Mendoza-Esquivel to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has not received a submission from Mendoza-Esquivel.

Based upon my review and consultations with BIS's Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Mendoza-Esquivel's export privileges under the Regulations for a period of 10 years from the date of Mendoza-Esquivel's conviction. I have also decided to revoke all licenses issued pursuant to the Act or Regulations in which Mendoza-Esquivel had an interest at the time of his conviction.

Accordingly, it is hereby *Ordered:*

First, from the date of this Order until August 11, 2025, Francisco Javier Mendoza-Esquivel, with a last known address of Register Number: 62841–179, Federal Correctional Institution, 2001 Rickabaugh Drive, Big Spring, TX 79720, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (the "Denied Person"), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

---

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2016). The Regulations issued pursuant to the Export Administration Act (50 U.S.C. 4601–4623 (Supp. III 2015) (available at *http://uscode.house.gov*)). Since August 21, 2001, the Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 4, 2016 (81 FR 52,587 (Aug. 8, 2016)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.* (2006 & Supp. IV 2010)).

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Mendoza-Esquivel by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Mendoza-Esquivel may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to the Mendoza-Esquivel. This Order shall be published in the **FEDERAL REGISTER**.

Sixth, this Order is effective immediately and shall remain in effect until August 11, 2025.

Issued this 14th day of September, 2016.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2016–22679 Filed 9–20–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

Advisory Committee on Supply Chain Competitiveness: Notice of Public Meetings

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of open meetings.

SUMMARY: This notice sets forth the schedule and proposed topics of discussion for public meetings of the Advisory Committee on Supply Chain Competitiveness (Committee).

DATES: The meetings will be held on October 19, 2016, from 12:00 p.m. to 3:00 p.m., and October 20, 2016, from 9:00 a.m. to 4:00 p.m., Eastern Standard Time (EST).

ADDRESSES: The meetings on October 19 and 20 will be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Research Library (Room 1894), Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Richard Boll, Office of Supply Chain, Professional & Business Services (OSCPBS), International Trade Administration. (Phone: (202) 482–1135 or Email: *richard.boll@trade.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Committee was established under the discretionary authority of the Secretary of Commerce and in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2). It provides advice to the Secretary of Commerce on the necessary elements of a comprehensive policy approach to supply chain competitiveness designed to support U.S. export growth and national economic competitiveness, encourage innovation, facilitate the movement of goods, and improve the competitiveness of U.S. supply chains for goods and services in the domestic and global economy; and provides advice to the Secretary on regulatory policies and programs and investment priorities that affect the competitiveness of U.S. supply chains. For more information about the Committee visit: *http://trade.gov/td/services/oscpb/supplychain/acscc/.*

Matters To Be Considered: Committee members are expected to continue to discuss the major competitiveness-related topics raised at the previous Committee meetings, including trade and competitiveness; freight movement and policy; information technology and data requirements; regulatory issues; finance and infrastructure; and workforce development. The Committee's subcommittees will report on the status of their work regarding these topics. The agendas may change to accommodate Committee business. The Office of Supply Chain, Professional & Business Services will post the final detailed agendas on its Web site, *http://trade.gov/td/services/oscpb/supplychain/acscc/,* at least one week prior to the meeting.

The meetings will be open to the public and press on a first-come, first-served basis. Space is limited. The public meetings are physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Mr. Richard Boll, at (202) 482–1135 or *richard.boll@trade.gov* five (5) business days before the meeting.

Interested parties are invited to submit written comments to the Committee at any time before and after the meeting. Parties wishing to submit written comments for consideration by the Committee in advance of this meeting must send them to the Office of Supply Chain, Professional & Business Services, 1401 Constitution Ave. NW., Room 11014, Washington, DC 20230, or email to *richard.boll@trade.gov.*

For consideration during the meetings, and to ensure transmission to the Committee prior to the meetings, comments must be received no later than 5:00 p.m. EST on October 12, 2016. Comments received after October 12, 2016, will be distributed to the Committee, but may not be considered at the meetings. The minutes of the meetings will be posted on the Committee Web site within 60 days of the meeting.

In addition, this notice expands the comment period on the ACSCC Freight Policy and Movement Subcommittee's recommendation that was discussed on ACSCC conference call held on September 7, 2016 to October 1, 2016. The recommendation will be available on the ACSCC Web site, *http://trade.gov/td/services/oscpb/supplychain/acscc/.* Written comments are due by close of business on October 1, 2016. Parties wishing to submit written comments regarding this recommendation must send them to the Office of Supply Chain, Professional & Business Services, 1401 Constitution Ave. NW., Room 11014, Washington, DC 20230, or email to *richard.boll@trade.gov.*

The Office of Supply Chain, Professional & Business Services will post the draft recommendations and the final agenda on the Committee Web site at least one week prior to the meeting. Please provide any comments on the draft recommendations to Richard Boll, Office of Supply Chain, Professional & Business Services, International Trade Administration. (Phone: (202) 482–1135 or Email: *richard.boll@trade.gov*) at least six days prior to the conference call, in order to ensure adequate time to distribute the comments for Committee review. The conference call will be open to the public for comments on a first-come, first-served basis, with thirty minutes available for public comments. Access lines are limited. The minutes of the meetings will be posted on the Committee Web site within 60 days of the meeting.

Dated: September 15, 2016.

Maureen Smith,

Director, Office of Supply Chain.

[FR Doc. 2016–22654 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–870]

Notice of Final Results of Antidumping Duty Changed Circumstances Review: Oil Country Tubular Goods From the Republic of Korea

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 18, 2016, the Department of Commerce (the Department) published the notice of initiation and preliminary results of the changed circumstances review of the antidumping duty order on oil country tubular goods from the Republic of Korea (Korea). In that notice, we preliminarily determined that Hyundai Steel Corporation (Hyundai Steel) is the successor-in-interest to Hyundai HYSCO (HYSCO) for purposes of determining antidumping duty cash deposits and liabilities. No interested party submitted comments on the preliminary results. For these final results, the Department continues to find that Hyundai Steel is the successor-in-interest to HYSCO.

DATES: Effective August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Victoria Cho, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5075.

SUPPLEMENTARY INFORMATION:

Background

On February 24, 2016, Hyundai Steel informed the Department that, effective July 1, 2015, it merged with HYSCO and requested that the Department conduct an expedited changed circumstances review under section 751(b) of the Tariff Act of 1930, as amended, 19 CFR 351.216(c), and 19 CFR 351.221(c)(3)(ii), to confirm that Hyundai Steel is the successor-in-interest to HYSCO for purposes of determining antidumping duty cash deposits and liabilities. On July 18, 2016, the Department initiated this changed circumstances review and published the notice of preliminary results,[1] determining that Hyundai Steel is the successor-in-interest to HYSCO.

Scope of the Order

The merchandise covered by the order is OCTG, which are hollow steel products of circular cross-section, including oil well casing and tubing, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, regardless of end finish (*e.g.,* whether or not plain end, threaded, or threaded and coupled) whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished (including limited service OCTG products) or unfinished (including green tubes and limited service OCTG products), whether or not thread protectors are attached. The scope of the investigation also covers OCTG coupling stock.

Excluded from the scope of the order are: Casing or tubing containing 10.5 percent or more by weight of chromium; drill pipe; unattached couplings; and unattached thread protectors.

The merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7304.29.10.10, 7304.29.10.20, 7304.29.10.30, 7304.29.10.40, 7304.29.10.50, 7304.29.10.60, 7304.29.10.80, 7304.29.20.10, 7304.29.20.20, 7304.29.20.30, 7304.29.20.40, 7304.29.20.50, 7304.29.20.60, 7304.29.20.80, 7304.29.31.10, 7304.29.31.20, 7304.29.31.30, 7304.29.31.40, 7304.29.31.50, 7304.29.31.60, 7304.29.31.80, 7304.29.41.10, 7304.29.41.20, 7304.29.41.30, 7304.29.41.40, 7304.29.41.50, 7304.29.41.60, 7304.29.41.80, 7304.29.50.15, 7304.29.50.30, 7304.29.50.45, 7304.29.50.60, 7304.29.50.75, 7304.29.61.15, 7304.29.61.30, 7304.29.61.45, 7304.29.61.60, 7304.29.61.75, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.29.10.30, 7306.29.10.90, 7306.29.20.00, 7306.29.31.00, 7306.29.41.00, 7306.29.60.10, 7306.29.60.50, 7306.29.81.10, and 7306.29.81.50.

The merchandise subject to the order may also enter under the following HTSUS item numbers: 7304.39.00.24, 7304.39.00.28, 7304.39.00.32, 7304.39.00.36, 7304.39.00.40, 7304.39.00.44, 7304.39.00.48, 7304.39.00.52, 7304.39.00.56, 7304.39.00.62, 7304.39.00.68, 7304.39.00.72, 7304.39.00.76, 7304.39.00.80, 7304.59.60.00, 7304.59.80.15, 7304.59.80.20, 7304.59.80.25, 7304.59.80.30, 7304.59.80.35, 7304.59.80.40, 7304.59.80.45, 7304.59.80.50, 7304.59.80.55, 7304.59.80.60, 7304.59.80.65, 7304.59.80.70, 7304.59.80.80, 7305.31.40.00, 7305.31.60.90, 7306.30.50.55, 7306.30.50.90, 7306.50.50.50, and 7306.50.50.70.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the order is dispositive.

Final Results of Changed Circumstances Review

For the reasons stated in the *Initiation and Preliminary Results,* and because we received no comments from interested parties, the Department finds that Hyundai Steel is the successor-in-interest to HYSCO. As a result of this determination, we find that Hyundai Steel should receive the cash deposit rate assigned to HYSCO in the most recently completed segment of the antidumping duty order on OCTG from Korea.[2] Consequently, the Department will instruct U.S. Customs and Border Protection to suspend liquidation of all shipments of subject merchandise produced or exported by Hyundai Steel and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at 6.49 percent, which is the current antidumping duty cash-deposit rate for HYSCO. This cash deposit requirement shall remain in effect until further notice.

---

[1] *See Certain Oil Country Tubular Goods from the Republic of Korea: Initiation and Expedited Preliminary Results of Changed Circumstances Review,* 81 FR 46645 (July 18, 2016) (*Initiation and Preliminary Results*).

[2] *See Certain Oil Country Tubular Goods From the Republic of Korea: Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances,* 79 FR 41983 (July 18, 2014) and *see also Certain Oil Country Tubular Goods From the Republic of Korea: Notice of Court Decision Not in Harmony With Final Determination,* 81 FR 59603 (August 30, 2016).

Dated: September 14, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–22768 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Marine Recreational Information Program Fishing Effort Survey.

OMB Control Number: 0648–0652.

Form Number(s): None.

Type of Request: Regular (revision and extension of a currently approved information collection).

Number of Respondents: 110,000.

Average Hours per Response: 10 minutes.

Burden Hours: 18,333.

Needs and Uses: Marine recreational anglers are surveyed to collect catch and effort data, fish biology data, and angler socioeconomic characteristics. These data are required to carry out provisions of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), as amended, regarding conservation and management of fishery resources.

Marine recreational fishing catch and effort data are collected through a combination of mail surveys, telephone surveys and on-site intercept surveys with recreational anglers. Amendments to the Magnuson-Stevens Fishery Conservation and Management Act (MSA) require the development of an improved data collection program for recreational fisheries. To partially meet these requirements, NOAA Fisheries designed and implemented the MRIP Fishing Effort Survey (FES) to ensure better coverage and representation of recreational fishing activity.

The FES is a self-administered, household mail survey that samples from a residential address frame to collect data on the number of recreational anglers and the number of recreational fishing trips. The survey estimates marine recreational fishing activity for all coastal states from Maine through Texas.

FES estimates are combined with estimates derived from independent but complementary surveys of fishing trips, the Access-Point Angler Intercept Survey, to estimate total, state-level fishing catch, by species. These estimates are used in the development, implementation, and monitoring of fishery management programs by NOAA Fisheries, regional fishery management councils, interstate marine fisheries commissions, and state fishery agencies.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: September 15, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–22647 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Tilefish Individual Fishing Quota (IFQ) Program.

OMB Control Number: 0648–0590.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 12.

Average Hours per Response: IFQ Allocation Permit Application, 30 minutes; IFQ Holder Cap Form, 5 minutes; IFQ Transfer Form, 5 minutes; IFQ Cost Recovery, 2 hours; IFQ Reporting Requirements, 2 minutes.

Burden Hours: 42.

Needs and Uses: This request is for extension of a current information collection.

National Marine Fisheries Service (NMFS) Greater Atlantic Region manages the golden tilefish fishery of the Exclusive Economic Zone (EEZ) of the Northeastern United States, through the Tilefish Fishery Management Plan (FMP). The Mid-Atlantic Fishery Management Council prepared the FMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The regulations implementing the FMP are specified at 50 CFR part 648 subpart N.

The recordkeeping and reporting requirements at § 648.294 form the basis for this collection of information. NMFS requests information from tilefish individual fishing quota (IFQ) permit holders in order to process applications to ensure that IFQ allocation holders are provided a statement of their annual catch quota, and for enforcement purposes, to ensure vessels are not exceeding an individual quota allocation. In conjunction with the application, NMFS also collects IFQ share accumulation information to ensure that an IFQ allocation holder does not acquire an excessive share of the total limited access privileges, as required by section 303A(d)(5)(C) of the Magnuson-Stevens Act.

NMFS requests transfer application information to process and track requests from allocation holders to transfer quota allocation (permanent and temporary) to another entity. NMFS also collects information for cost recovery purposes as required under the Magnuson-Stevens Act to collect fees to recover the costs directly related to management, data collection and analysis, and enforcement of IFQ programs. Lastly, NMFS collects landings information to ensure that the amounts of tilefish landed and ex-vessel prices are properly recorded for quota monitoring purposes and the calculation of IFQ fees, respectively. Having this information results in an increasingly more efficient and accurate database for management and monitoring of fisheries of the Northeastern U.S. EEZ.

Affected Public: Business or other for-profit organizations.

Frequency: Annually and on occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: September 15, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–22648 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Deposit of Biological Materials

ACTION: Notice and request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the renewal of a continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before November 21, 2016.

ADDRESSES: You may submit comments by any of the following methods:

- *Email: InformationCollection@uspto.gov*. Include "0651–0022 comment" in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov*.
- *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email to *Raul.Tamayo@uspto.gov* with "0651–0022 comment" in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under "Information Collection Review."

SUPPLEMENTARY INFORMATION:

I. Abstract

This information collection covers both deposits of biological materials and the depositories in which they are stored. While these two topics are related, the information collection requirements for a respondent depositing biological material are not the same as those that must be followed by a respondent seeking approval from the USPTO to store biological materials. These different requirements are addressed in separate sections. Section I.A. deals with the deposit of biological materials and section I.B. deals with the depositories. There are no forms associated with this collection.

A. Deposits of Biological Materials

The deposit of biological materials as part of a patent application is authorized by 35 U.S.C. 2(b)(2). The term "biological material" is defined in 37 CFR 1.801 as including material that is capable of self-replication, either directly or indirectly. When an invention involves a biological material, sometimes words and figures are not sufficient to satisfy the statutory requirement for patentability under 35 U.S.C. 112 (every patent must contain a description of the invention sufficient to enable a person (knowledgeable in the relevant science), to make and use the invention as specified by 35 U.S.C. 112). In such cases, the required biological material must either be: (1) Known and readily available (neither condition alone is sufficient) or (2) deposited in a suitable depository that has been recognized as an International Depositary Authority (IDA) established under the Budapest Treaty, or a depository recognized by the USPTO to meet the requirements of 35 U.S.C. 112. Under the authority of 35 U.S.C. 2(b)(2), the deposit rules (37 CFR 1.801–1.809) set forth examining procedures and conditions of deposit which must be satisfied in the event a deposit is required. The rules do not address the substantive issue of whether a deposit is required under any particular set of facts.

In cases where a deposit is necessary, the USPTO collects information to determine whether the depositor is in compliance with the deposit rules. This includes statements proving notification to the interested public on where to obtain samples of the deposits and confirming that all restriction on access to the deposit will be irrevocably removed upon issuance of the patent. A viability statement also must be submitted to the USPTO showing that the biological material was tested by the depository or another, the conditions of the test, and that it is a viable or acceptable deposit. A viability statement is not required when a deposit is made and accepted under the Budapest Treaty.

Once a depositor has deposited biological materials into a recognized depository, occasions may arise necessitating additional communication between the depositor and the USPTO. For example, depositors may be required to submit verification statements for biological materials deposited after the effective filing date of a patent application or written notification that an acceptable deposit will be made.

Occasionally a deposit may be lost, contaminated, or otherwise is not able to self-replicate, and a replacement or supplemental deposit needs to be made. In that event, the depositor must submit a written notification to the USPTO concerning the particulars of the situation and request a certificate of correction by the USPTO authorizing the replacement or supplemental deposit.

To summarize, the nature of the information collected by the USPTO in association with the deposit of biological materials is that of certifications/statements, as described above, regarding a biological sample deposited at a depository. There is no form associated with the information collected by the USPTO in connection with the deposit of biological materials.

B. Depositories

Institutions that wish to be recognized by the USPTO as a suitable depository to receive deposits for patent purposes are required by 37 CFR 1.803 to make a request demonstrating that they are qualified to store and test the biological materials submitted to them under patent applications. A depository seeking recognition from the USPTO to store biological materials must show that internal practices (both technical and administrative) and the technical ability of the staff and the facility are sufficient to protect the integrity of the biological materials being stored.

USPTO rules are stringent to ensure the competence and quality of depositories. Depositories must submit documentation to the USPTO that verifies that their practices and procedures, the technical competence of their staff, and their facilities fulfill the stringent requirements spelled out under the rules.

Once a depository has been recognized by the USPTO, occasions may arise where additional communication between the depository and the USPTO is necessary. For example, a depository must request and obtain written approval from the USPTO to handle additional types of biological materials other than the material originally recognized. Depositories may (on behalf of depositors) submit viability statements for deposits tested at the depository and/or documentation proving the public has been notified about where to obtain samples.

To summarize, the nature of the information collected by the USPTO in connection with a respondent seeking approval from the USPTO to store biological materials is that of a written request to the Director of the USPTO containing the information outlined above. There is no form for the request.

II. Method of Collection

By mail, hand delivery, or electronically to the USPTO.

III. Data

OMB Number: 0651–0022.

Form Number(s): None.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 901 responses per year. The USPTO estimates that approximately 3% of these responses will be from small entities.

Estimated Time per Response: The USPTO estimates that it will take the public 1 hour to gather the necessary information, prepare the appropriate form or documents, and submit the information to the USPTO for a deposit of biological materials. The USPTO estimates that it will take the average depository seeking approval to store biological materials approximately 5 hours to collect and submit the necessary approval information.

Estimated Total Annual Respondent Burden Hours: 905 hours.

Estimated Total Annual Respondent Cost Burden: $27,0327.55. The USPTO estimates a professional hourly rate of $30 for a senior administrative assistant to collect and submit the deposit information. The USPTO expects that the average depository seeking approval to store biological material will be prepared by attorneys at an estimated rate of $65.51 (BLS rate; 23–1011 Lawyers) per hour. Therefore, the USPTO estimates that the respondent cost burden for this collection will be approximately $27,327.55 per year.

No.	Item	Estimated time for response (minutes) (a)	Estimated annual responses (b)	Estimated annual burden hours (a) × (b)/60 = (c)	Rate ($/hr) e	Total costs (c) × (d) = (hourly cost burden)
1	Deposited Materials	1 hour	900	900	30	27,000
2	Depository Approval	5 hours	1	5	65.51	327.55
Total			901	905	....	27,327.55

Estimated Total Annual Non-hour Respondent Cost Burden: $2,674,644.45. There are no maintenance costs, recordkeeping costs, or filing fees associated with this information collection. However, this collection has annual (non-hour) costs in the form of capital start-up and postage costs.

Depositories charge fees to depositors; all depositories charge about the same rates for their services. For example, the American Type Culture Collection (ATCC), one of the world's leading biological supply houses and recognized patent depositories, offers comprehensive patent services for $2,500 per deposit. Most deposits received from outside the United States require an import permit from the U.S. Department of Agriculture (USDA) as well as a Public Health Service (PHS) permit, available from the Centers for Disease Control and Prevention (CDC), for importation of agents infectious to humans. There is no extra charge for this permit application processing. The USPTO estimates that the total non-hour respondent cost burden in the form of capital start-up costs amounts to $2,250,000.

In addition, this collection has postage costs. Biological deposits are generally shipped to the depository "Domestic Overnight" by Federal Express (FedEx) and, since depositors are urged to supply frozen or freeze-dried material, it must be packed in dry ice according to a representative from the Patent Department at ATCC. Dry ice itself is considered a dangerous good and requires special packaging. Additional FedEx special handling charges for inaccessible dangerous goods shipments of $40 per shipment apply for temperature-sensitive biological materials and also for the dry ice. An average cost for shipping by FedEx "Domestic Overnight" is estimated to be $75. If the shipment requires pick-up by FedEx, there is an additional charge of $4. Special packaging is also required for these shipments. According to DG Supplies Inc., a supplier of infectious and diagnostic goods packaging, the average cost of frozen infectious shippers is estimated to be $352.82 per package of four for specimen shipments requiring refrigeration or dry ice. Therefore, postage costs average $471.82 per shipment. The postage cost for a depository seeking recognition is estimated to be $6.45, sent to the USPTO by priority mail through the United States Postal Service. Since the USPTO estimates that it receives one request for recognition from a depository every four years, the average postage cost to respondents is $6.45 per year.

Item No.	Item/type of cost	Estimated annual responses	Amount	Totals
	FEES			
1	Deposited Materials	900	$2,500.00	$2,250,000

Item No.	Item/type of cost	Estimated annual responses	Amount	Totals
2	Request for Depository Approval	1	0.00	0.00
Total Fees				2,250,000
	PACKAGING/POSTAGE COSTS			
1	Deposited Materials—Federal Express	900	$119.00	$107,100.00
1	Deposited Materials—Packaging Supplies	900	352.82	317,538.00
2	Request for Depository Approval	1	6.45	6.45
Total Postage/Packaging				424,644.45
Total Annual (Non-Hour) Cost Burden				2,674,644.45

The USPTO estimates that the (non-hour) respondent cost burden in the form of mailing costs amounts to $424,644.45.

Therefore, the USPTO estimates that the total (non-hour) respondent cost burden for this collection in the form of capital start-up costs and postage costs is $2,674,644.45.

IV. Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

The USPTO is soliciting public comments to:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Dated: September 15, 2016.

Marcie Lovett,

Records Management Division Director, OCIO United States Patent and Trademark Office.

[FR Doc. 2016–22684 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–16–P

PATENT AND TRADEMARK OFFICE

Submission for OMB Review; Comment Request, Pro Bono Survey; Correction

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice; correction.

SUMMARY: The United States Patent and Trademark Office published a document in the **Federal Register** on August 22, 2016, concerning requests for comments on a Pro Bono Survey. The Pro Bono Survey is used by the Pro Bono Advisory Council (PBAC) and the USPTO to provide information to the USPTO regarding the current status and effectiveness of each region's pro bono hub. The document contained an incorrect cost burden based on the estimate of the hourly burden rate. The hourly rate estimate should use the Bureau of Labor Statistics hourly wage for lawyers instead of the American Intellectual Property Law Association hourly wage for intellectual property lawyers.

FOR FURTHER INFORMATION CONTACT: John Kirkpatrick, 571–270–3343 or email *InformationCollection@uspto.gov.* Include "Pro Bono Survey" in the subject line of the message.

Correction

In the **Federal Register** notice published on August 22, 2016 (81 FR 56612), in the second column, correct the "*Cost Burden*" caption to read:

Cost Burden: $10,480.00

Dated: September 13, 2016.

Marcie Lovett,

Records Management Division Director, USPTO Office of the Chief Information Officer.

[FR Doc. 2016–22683 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request; Legal Processes

The United States Patent and Trademark Office (USTPO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: United States Patent and Trademark Office, (USPTO).

Title: Legal Processes.

OMB Control Number: 0651–0046.

Form Number(s): None.

Type of Request: Renewal.

Number of Respondents: 309 responses per year.

Average Hours per Response: The USPTO estimates that it will take the public from 5 minutes (0.08 hours) to 6 hours to prepare a single item in this collection, including gathering the necessary information, preparing the appropriate documents, and submitting the information required for this collection.

Burden Hours: 130 hours.

Cost Burden: $8,479.54. The USPTO expects that the information in this collection will be prepared by attorneys and former employees at an hourly rate of $65.51. Using these hourly rates, the USPTO estimates that the total respondent cost burden for this collection will be approximately $8,479.54 per year.

Needs and Uses: The purpose of this collection is to cover information requirements related to civil actions and claims involving current and former employees of the United States Patent and Trademark Office (USPTO). The rules for these legal processes may be found under 37 CFR part 104, which outlines procedures for service of process, demands for employee testimony and production of documents in legal proceedings, reports of unauthorized testimony, employee indemnification, and filing claims against the USPTO under the Federal Tort Claims Act (28 U.S.C. 2672) and the corresponding Department of Justice regulations (28 CFR part 14). The public may also petition the USPTO Office of General Counsel under 37 CFR 104.3 to waive or suspend these rules in extraordinary cases.

The procedures under 37 CFR part 104 ensure that service of process intended for current and former employees of the USPTO is handled properly. The USPTO will only accept service of process for an employee acting in an official capacity. This collection is necessary so that respondents or their representatives can serve a summons or complaint on the USPTO, demand employee testimony and documents related to a legal proceeding, or file a claim under the Federal Tort Claims Act. Respondents may also petition the USPTO to waive or suspend these rules for legal processes. This collection is also necessary so that current and former USPTO employees may properly forward service and demands to the Office of General Counsel, report unauthorized testimony, and request indemnification. The USPTO covers current employees as respondents under this information collection even though their responses do not require approval under the Paperwork Reduction Act. In those instances where both current and former employees may respond to the USPTO, the agency estimates that the number of respondents will be small.

There are no forms provided by the USPTO for this collection. For filing claims under the Federal Tort Claims Act, the public may use Standard Form 95 "Claim for Damage, Injury, or Death," which is provided by the Department of Justice and approved by the Office of Management and Budget (OMB) under OMB Control Number 1105–0008.

Affected Public: Individuals or households; businesses or other for-profits; not-for-profit institutions; and the Federal Government.

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov.*

Once submitted, the request will be publicly available in electronic format through *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

- *Email: InformationCollection@uspto.gov.* Include "0651–0046" in the subject line of the message.
- *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before October 21, 2016 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Dated: September 15, 2016.

Marcie Lovett

Records Management Division Director, OCIO, United States Patent and Trademark Office.

[FR Doc. 2016–22682 Filed 9–20–16; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

Renewal of the Agricultural Advisory Committee

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (Commission) is publishing this notice to announce the renewal of the Agricultural Advisory Committee (AAC). The Commission has determined that the renewal of the AAC is necessary and in the public's interest, and the Commission has consulted with the General Services Administration's Committee Management Secretariat regarding the AAC's renewal.

FOR FURTHER INFORMATION CONTACT: Cory Claussen, AAC Designated Federal Officer, at 202–418–5383 or *cclaussen@cftc.gov.*

SUPPLEMENTARY INFORMATION: The AAC's objectives and scope of activities are to assist the Commission in assessing issues affecting agricultural producers, processors, lenders and others interested in or affected by the agricultural commodity derivatives markets through public meetings, and Committee reports and recommendations. The AAC will operate for two years from the date of renewal unless the Commission directs that the AAC terminate on an earlier date. A copy of the AAC renewal charter has been filed with the Commission; the Senate Committee on Agriculture, Nutrition and Forestry; the House Committee on Agriculture; the Library of Congress; and the General Services Administration's Committee Management Secretariat. A copy of the renewal charter will be posted on the Commission's Web site at *www.cftc.gov.*

Dated: September 16, 2016.

Christopher J. Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2016–22717 Filed 9–20–16; 8:45 am]

BILLING CODE 6351–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2009–0102]

Submission for OMB Review; Comment Request—Follow-Up Activities for Product-Related Injuries

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Consumer Product Safety Commission (Commission or CPSC) announces that it has submitted to the Office of Management and Budget (OMB) a request for extension of approval of a collection of information from persons who have been involved in or have witnessed incidents associated with consumer products.

DATES: Written comments on this request for extension of approval of information collection requirements should be submitted by October 21, 2016.

ADDRESSES: OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified by Docket No. CPSC–2009–0102. In addition, written comments also should be submitted at *http://www.regulations.gov,* under Docket No. CPSC–2009–0102, or by mail/hand delivery/courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Robert H. Squibb, U.S. Consumer Product Safety Commission, 4330 East

West Highway, Bethesda, MD 20814; telephone: 301–504–7923 or by email to *rsquibb@cpsc.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 22, 2016 (81 FR 40677), the CPSC published a notice in accordance with provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) to announce the CPSC's intention to seek extension of approval of a collection of information on product-related injuries or incidents. No comments were received in response to that notice. Therefore, by publication of this notice, the Commission announces that it has submitted to OMB a request for extension of approval of that collection of information without change.

A. Background

Section 5(a) of the Consumer Product Safety Act, 15 U.S.C. 2054(a), requires the Commission to collect information related to the causes and prevention of death, injury, and illness associated with consumer products. That section also requires the Commission to conduct continuing studies and investigations of deaths, injuries, diseases, other health impairments, and economic losses resulting from accidents involving consumer products.

The Commission obtains information about product-related deaths, injuries, and illnesses from a variety of sources, including newspapers, death certificates, consumer complaints, and medical facilities. In addition, the Commission receives information through its Internet Web site through forms reporting on product-related injuries or incidents.

The Commission also operates a surveillance system known as the National Electronic Injury Surveillance System (NEISS) that provides timely data on consumer product-related injuries treated as well as U.S. childhood poisonings. NEISS data comes from a statistically valid sample from approximately 100 hospital emergency departments. The NEISS system has been in operation since 1971. NEISS emergency department records are reviewed by hospital employees or contractors (NEISS respondents).

From these sources, Commission staff selects cases of interest for further investigation by face-to-face or telephone interviews with persons who witnessed, or were injured in, incidents involving consumer products. The CPSC plans to begin conducting investigations through internet-based questionnaires in the next year to supplement telephone interviews. On-site investigations are usually made in cases where CPSC staff need photographs of the incident site, the product involved, or detailed information about the incident. This information can come from face-to-face interviews with persons who were injured or who witnessed the incident, as well as contact with state and local officials, including police, coroners, and fire investigators, and others with knowledge of the incident.

The Commission uses the information to support the development and improvement of voluntary standards; rulemaking proceedings; information and education campaigns; compliance and enforcement efforts and related administrative and judicial proceedings. Commission activities are, in many cases, data driven, and incident data is crucial in advancing the agency's mission. In addition, the CPSC also collects information through NEISS for other federal agencies through Interagency Agreements including the Centers for Disease Control and Prevention (CDC) and the National Highway Traffic Safety Administration (NHTSA).

OMB approved the collection of information concerning product-related injuries under control number 3041–0029. OMB's most recent extension of approval will expire on September 30, 2016. The Commission now proposes to request an extension of approval of this collection of information.

B. NEISS Estimated Burden

The NEISS system collects information on consumer-product related injuries from about 100 hospitals in the U.S. Respondents to NEISS include hospitals that directly report information to NEISS and hospitals that allow CPSC contractors to collect the data on behalf of the agency. In FY 2015, there were 137 NEISS respondents (total hospitals and CPSC contractors). The NEISS respondents reviewed an estimated 5.05 million emergency department records and reported 739,673 total cases.

Collecting emergency department records for review each day takes about 10 minutes. Each record takes about 30 seconds to review. Coding and reporting records that involve consumer products or other injuries takes about 2 minutes per record. Coding and reporting additional special study information takes about 90 seconds per record. Respondents also spend about 36 hours per year in related activities (training, evaluations, and communicating with other hospital staff).

The total burden hours for all NEISS respondents are estimated to be 81,210 for FY2015. The average burden hour per respondent is 593 hours. However, the total burden hour on each respondent varies due to differences in size of the hospital (*e.g.,* small rural hospitals versus large metropolitan hospitals). The smallest hospital reported 202 cases with a burden of about 111 hours, while the largest hospital reported 60,405 cases with a burden of about 4,222 hours.

The total costs to NEISS respondents for FY2015 are estimated to be $3,271,621 per year. NEISS respondents enter into contracts with CPSC and are compensated for these costs. The average cost per respondent is estimated to be about $23,880. The average cost per burden hour is estimated to be $40.29 per hour (including wages and overhead). However, the actual cost to each respondent varies due to the type of respondent (hospital versus CPSC contractor), size of hospital, and regional differences in wages and overhead. Therefore, the actual annual cost for any given respondent may vary between $1,199 at a small rural hospital and $281,953 at the largest metropolitan hospital.

C. Other Burden Hours

In cases that require more information regarding product-related incidents or injuries, the CPSC staff conducted face-to-face interviews of approximately 220 persons each year. On average, an on-site interview takes about 4.5 hours. CPSC staff also conducts about 1760 in-depth investigations by telephone. Each in-depth telephone investigation requires about 20 minutes. In addition, staff is planning to conduct about 200 internet-based questionnaires per year that require about 20 minutes each.

The CPSC staff estimates 1,643 annual burden hours on these respondents: 989 hours for face-to-face interviews; 587 hours for in-depth telephone interviews, and 67 hours for internet-based questionnaires. The burden required for reporting is estimated at $32.82 an hour (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2016, Table 9, Total compensation for all sales and office workers in goods-producing industries: *http://www.bls.gov/ncs*). At this valuation, the estimated annual cost to the public is about $53,923.

This request for the approval of an estimated 82,853 (81,210 NEISS and 1,643 other) burden hours per year is an increase of 37,845 hours since this collection of information was last approved by OMB in 2013. The increase in the burden hours is largely due to the inclusion of information collected through NEISS for other federal agencies through Interagency Agreements including CDC and NHTSA, which were not otherwise accounted for by those agencies. In order to account for all the burden hours associated with the NEISS information collection, we have added those hours to the collection of information. The increase in burden hours also includes the increase associated with offering internet-based questionnaires in addition to in-person and telephone interviews.

This information collection request excludes the burden associated with other publicly available Consumer Product Safety Information Databases, such as internet complaints, Hotline, and Medical Examiners and Coroners Alert Project (MECAP) reports, which are approved under OMB control number 3041–0146. This information collection request also excludes the burden associated with follow-up investigations conducted by other federal agencies.

The annual cost to the government of the collection of the NEISS information is estimated to be about $4.9 million a year. This estimate includes $3.3 million in compensation to NEISS respondents described in section 12(a) above. This estimate also includes $1.603 million for about 150 CPSC professional staff months each year. The estimate of professional staff months includes the time required to: Oversee NEISS operations (*e.g.,* administration, training, quality control); prepare questionnaires, interviewer guidelines, and other instruments and instructions used to collect the information; conduct face-to-face and telephone interviews; and evaluate responses obtained from interviews and completed forms. Each month of professional staff time costs the Commission about $10,683.83. This is based on a GS–12 mid-level salaried employee. The average yearly wage rate for a mid-level salaried GS–12 employee in the Washington, DC metropolitan area (effective as of January 2016) is $87,821 (GS–12, step 5). This represents 68.5 percent of total compensation (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2016, Table 1, percentage of wages and salaries for all civilian management, professional, and related employees: *http://www.bls.gov/ncs/*). Adding an additional 31.5 percent for benefits brings average yearly compensation for a mid-level salaried GS–12 employee to $128,206.

Dated: September 16, 2016.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2016–22696 Filed 9–20–16; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Amendment of Department of Defense Federal Advisory Committees

AGENCY: Department of Defense.

ACTION: Amend Federal Advisory Committee Charter.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce it is amending the charter for the Air University Board of Visitors.

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: This committee's charter is being amended in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended) and 41 CFR 102–3.50(d). The amended charter and contact information for the Designated Federal Officer (DFO) can be obtained at *http://www.facadatabase.gov/*. The DoD is amending the charter for the Air University Board of Visitors ("the Board") previously published in the **Federal Register** on April 14, 2016 (81 FR 22066). The Board's charter is being amended to update the estimated number of Board meetings to two per year. All other aspects of the Board's charter, as previously published, and amended as previously published in the **Federal Register** on July 27, 2016 (81 FR 49214), will apply to the Board.

Dated: September 16, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–22693 Filed 9–20–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 15–55]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

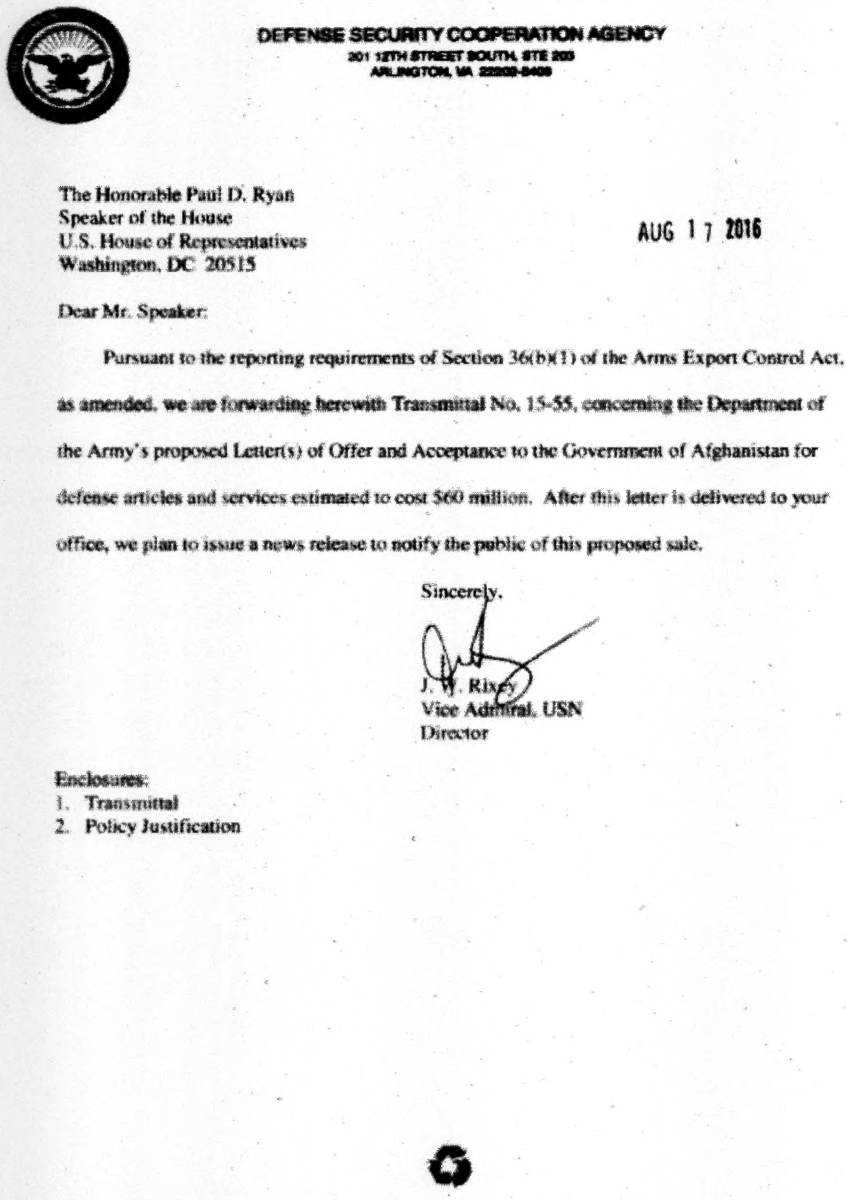
FOR FURTHER INFORMATION CONTACT: Chang Sug, DSCA/LMO, (703) 697–8985.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 15–55 with attached Policy Justification.

Dated: September 16, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

AUG 17 2016

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-55, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to the Government of Afghanistan for defense articles and services estimated to cost $60 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification

Transmittal No. 15–55

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b) (1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Afghanistan

(ii) *Total Estimated Value:*

Major Defense Equipment*	$30.0 million
Other	$30.0 million
TOTAL	$60.0 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Four thousand, eight hundred and ninety-one (4,891) M16A4 5.56mm Rifles, Four hundred and eighty-five (485) M240B 7.62mm Machine Guns, Eight hundred (800) M2 .50 caliber Machine Guns.

Non-MDE: Also included with this request are M249 Light Automatic Machine Guns; M110 7.62mm Sniper Rifles; MK–19 40mm Grenade Launchers; MK–93 40mm Machine Gun Mounts; M3 Tripod Machine Gun Mounts; Spare Barrels; spare and repair parts; lot validation; publications and technical documentation; personnel training and training equipment; Quality Assurance Team; U.S. Government and contractor technical and logistics support services; and other related elements of logistics and program support.

(iv) *Military Department:* Army (UBY)

(v) *Prior Related Cases, if any:*

FMS case B6–B–FAK—$138.8M—Nov 2007; FMS case E3–B–UAF—$39.0M—Aug 2008; FMS case E6–B–UBN—$55.0M—Jul 2009; FMS case AF–B–UBI—$3.3M—Jan 2010; FMS case G5–B–UAG—$39.0M—Mar 2010; FMS case G5–B–UEQ—$11.0M—Nov 2010; FMS case G5–B–UEK—$152.5M—Nov 2010; FMS case G6–B–UBD—$20.2M—Apr 2011; FMS case G6–B–UBI—$512.6M—May 2011; FMS case H5–B–UCN—$20.8M—Dec 2012; FMS case H5–B–UES—$1.8M—Aug 2013; FMS case J3–B–UCJ—$50.9M—Mar 2015; FMS case J3–B–UDE—$2.7M—Apr 2015; FMS case J3–B–UEW—$5.66M—Sep 2015; FMS case J8–B–UAI—$21M—May 2015; FMS case J8–B–UAN—$7.6M—Jul 2015; FMS case V3–B–UAP—$9M—Apr 2016

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None.

(viii) *Date Report Delivered to Congress:* 2016 AUG 17.

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Afghanistan—Individual and Crew Served Weapons

The Government of Afghanistan has requested a possible sale of:

Major Defense Equipment (MDE):

Four thousand, eight hundred and ninety-one (4,891) M16A4 5.56mm Rifles, Four hundred and eighty-five (485) M240B 7.62mm Machine Guns, Eight hundred (800) M2 .50 caliber Machine Guns.

Non-MDE:

Also included with this request are M249 Light Automatic Machine Guns; M110 7.62mm Sniper Rifles; MK–19 40mm Grenade Launchers; MK–93 40mm Machine Gun Mounts; M3 Tripod Machine Gun Mounts; Spare Barrels; spare and repair parts; lot validation; publications and technical documentation; personnel training and training equipment; Quality Assurance Team; U.S. Government and contractor technical and logistics support services; and other related elements of logistics and program support. The estimated cost is $60 million.

The proposed sale will enhance the foreign policy and national security objectives of the United States by helping to improve the security of a strategic partner by providing weapons needed to maintain security and stability, as well as to conduct offensive operations against an ongoing insurgency. A stable and secure Afghanistan is vital to regional stability. This proposed sale will also demonstrate the U.S. commitment to Afghanistan's security.

Afghanistan has an urgent requirement to increase its stocks of crew-served weapons for ongoing counter-insurgency operations and enduring threats to its national sovereignty. These articles were determined to be necessary and are based on Afghanistan's force structure and operational requirements.

The Afghan National Army (ANA) will use these weapons and equipment in both offensive and defensive operations against insurgents and terrorists within their borders. Without these defense articles, the ANA will not have the military capabilities that are necessary to maintain security and stability. The ANA is thoroughly trained and prepared to use the proposed defense articles. Afghanistan will have no difficulty absorbing this equipment into its armed forces.

While equipment for the ANA is typically purchased with Title 10 Afghanistan Security Forces Fund (ASFF) appropriations and implemented by DSCA through pseudo-FMS cases, Afghanistan will use U.S. government grants to fund and support this proposed purchase.

The principal contractor for the M240B will be FN America, Colombia, SC. The principal contractors for the M16A4, M2, and other weapons have not been identified pending open competition and contract award. Some items may be drawn from Army stocks to meet desired delivery dates. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this sale will require the assignment of approximately eight (8) additional U.S. Government and approximately six (6) contractor representatives to Afghanistan for approximately 5–6 weeks in support of the fielding, maintenance and personnel training.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2016–22692 Filed 9–20–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 16–29]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

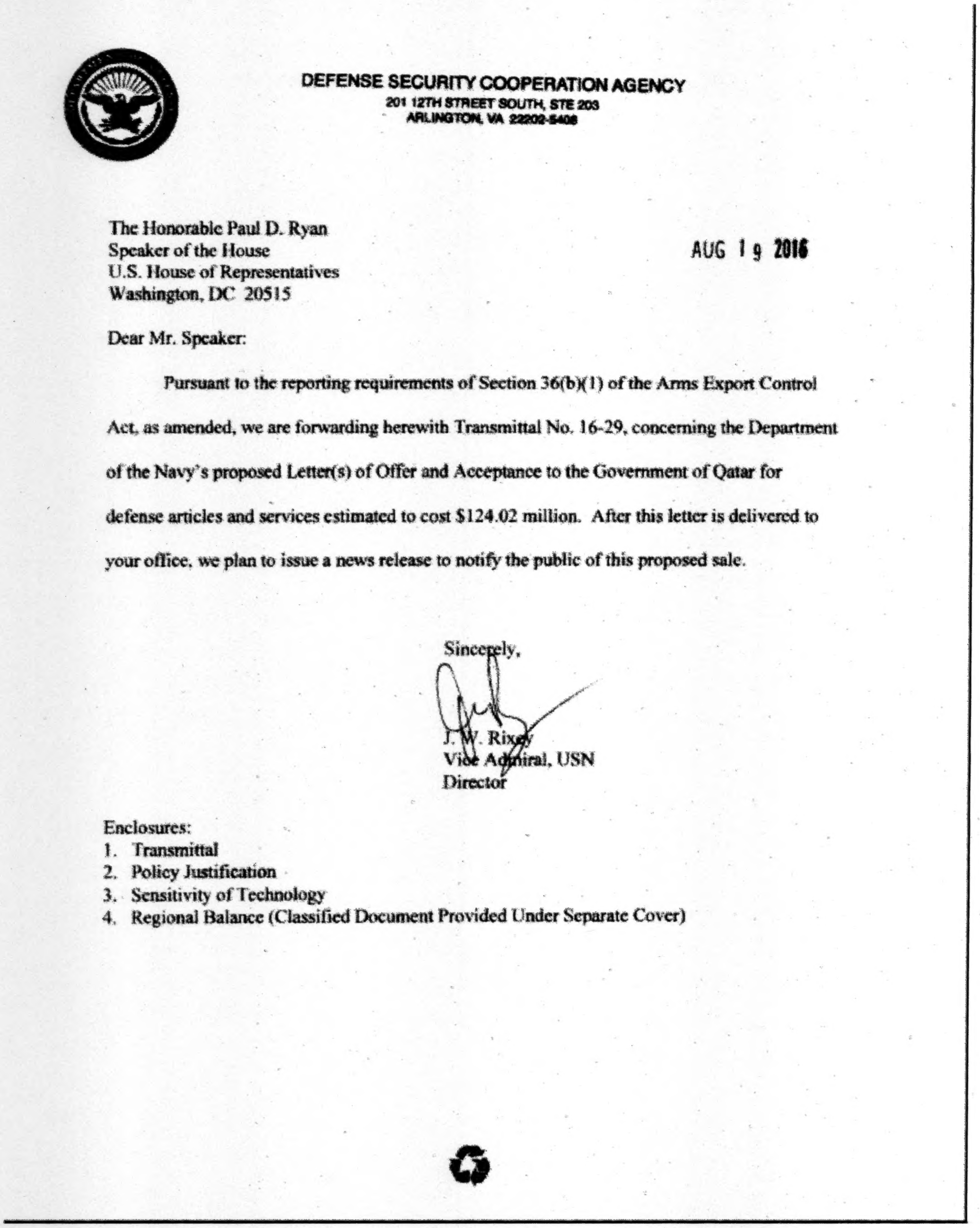
FOR FURTHER INFORMATION CONTACT: Chang Sug, DSCA/STR/LMO, (703) 697–8985.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 16–29 with attached Policy Justification and Sensitivity of Technology.

Dated: September 15, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

AUG 19 2016

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-29, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Qatar for defense articles and services estimated to cost $124.02 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 16–29

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Qatar

(ii) *Total Estimated Value:*

Major Defense Equipment *	$0.02 million
Other	$124.00 million
TOTAL	$124.02 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Eight (8) M2HB .50 Caliber Machine Guns.

Non-MDE: Also included are Mk-V Fast Patrol Boats, Forward Looking Infrared (FLIR) Systems, MLG 27mm Gun Systems, 27mm ammunition, 27mm target practice ammunition, .50 Caliber ammunition, support equipment, publications, technical documentation, personnel training, U.S. Government and contractor engineering, in-country support, technical and logistics support services.

(iv) *Military Department:* Navy

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached annex.

(viii) *Date Report Delivered to Congress:* 19 AUG 2016.

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Qatar—Mk-V Fast Patrol Boat

The Government of Qatar has requested:

Major Defense Equipment (MDE): Eight (8) M2HB .50 Caliber Machine Guns.

Non-MDE:

Also included are Mk-V Fast Patrol Boats, Forward Looking Infrared (FLIR) Systems, MLG 27mm Gun Systems, 27mm ammunition, 27mm target practice ammunition, .50 Caliber ammunition, support equipment, publications, technical documentation, personnel training, U.S. Government and contractor engineering, in-country support, technical and logistics support services.

The total estimated value of MDE is $0.02 million. The total estimated value is $124.02 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country. Qatar is an important force for political stability and economic progress in the Persian Gulf region. This proposed sale will provide Qatar with military capabilities to protect its critical sea-based infrastructure and maritime security. Qatar will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment, services, and support will not alter the basic military balance in the region.

The principal contractor will be United States Marine Incorporated (USMI) in Gulfport, Mississippi. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require multiple trips by U.S. Government and contractor representatives to participate in program and technical reviews, system integration, as well as training and maintenance support in country for a period of five (5) years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 16–29

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

Annex Item No. vii

(vii) *Sensitivity of Technology:*

1. The Mk-V fast patrol boat is approximately twenty-eight meters (28) long with an approximate beam of six (6) meters powered by MTU diesel engines with a waterjet drive. It has a top speed of forty-five (45) knots. The MK-V is outfitted with a stern launch-able inflatable boat. The MK-V is outfitted with unclassified commercial off-the-shelf navigation to include magnetic compass, fluxgate compass, gyro compass, Global Positioning System (GPS), electronic chart plotter, anemometer, navigation radar, navigation lights, navigation horn siren, and other electrical and non-electronic navigation aids. The MK-V utilizes commercial communications to include high frequency (HF), and very high frequency (VHF) communication radio systems, intercom system, boat horn and blue strobe law enforcement lights. The overall classification level of the vessel is UNCLASSIFIED.

2. A determination has been made that the Government of Qatar can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of U.S. foreign policy and national security objectives outlined in the Policy Justification.

3. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Qatar.

[FR Doc. 2016–22655 Filed 9–20–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2013–OS–0072]

Proposed Collection; Comment Request

AGENCY: United States Military Entrance Processing Command (USMEPCOM), Office of the Under Secretary of Defense (Personnel and Readiness) (Military Personnel Policy), DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the United States Military Entrance Processing Command (USMEPCOM), Office of the Under Secretary of Defense (Personnel and Readiness) (Military Personnel Policy) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by November 21, 2016.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the HQ USMEPCOM Program Analysis and Evaluation Directorate, ATTN: Mr. Donald Wnuk, 2834 Green Bay Road, North Chicago, IL 60064–3094; call at 847–688–3680, Extension 7235, or email at *donald.j.wnuk.civ@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: USMEPCOM MEPS Customer Satisfaction Survey, OMB Control Number 0704–0470.

Needs and Uses: The information collection requirement is necessary to aid the MEPS in evaluating effectiveness of current policies and core processes, identifying unmet customer needs, and allocating resources more efficiently.

Affected Public: Individuals or households.

Annual Burden Hours: 12,500.

Number of Respondents: 75,000.

Responses per Respondent: 1.

Annual Responses: 1.

Average Burden per Response: 10 minutes.

Frequency: On occasion.

USMEPCOM, with headquarters in North Chicago, Ill., is a joint service command staffed with civilians and military from all five branches of service. The command, through its network of 65 Military Entrance Processing Stations, determines whether applicants are qualified for enlistment based on standards set by each of the services. USMEPCOM Regulation 601–23, Enlistment Processing, directs the information collection requirement for all 65 Military Entrance Processing Stations (MEPS) to obtain timely feedback on MEPS core processes. This web-based tool will allow MEPS to efficiently administer voluntary surveys on a routine basis to their primary customer, the applicants, for military service. This information collection requirement is necessary to aid the MEPS in evaluating effectiveness of current policies and core processes, identifying unmet customer needs, and allocating resources more efficiently.

Dated: September 16, 2016.

Aaron Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2016–22695 Filed 9–20–16; 8:45 am]

BILLING CODE 5001–06–P

DENALI COMMISSION

Fiscal Year 2017 Draft Work Plan

AGENCY: Denali Commission.

ACTION: Notice.

SUMMARY: The Denali Commission (Commission) is an independent federal agency based on an innovative federal-state partnership designed to provide critical utilities, infrastructure and support for economic development and training in Alaska by delivering federal services in the most cost-effective manner possible. The Commission was created in 1998 with passage of the October 21, 1998 Denali Commission Act (Act) (Title III of Pub. L. 105–277, 42 U.S.C. 3121). The Act requires that the Commission develop proposed work plans for future spending and that the annual Work Plan be published in the **Federal Register**, providing an opportunity for a 30-day period of public review and written comment. This **Federal Register** notice serves to announce the 30-day opportunity for public comment on the Denali Commission Draft Work Plan for Federal Fiscal Year 2017 (FY 2017).

DATES: Comments and related material to be received by October 21, 2016.

ADDRESSES: Submit comments to the Denali Commission, Attention: Sabrina Cabana, 510 L Street, Suite 410, Anchorage, AK 99501.

FOR FURTHER INFORMATION CONTACT: Ms. Sabrina Cabana, Denali Commission, 510 L Street, Suite 410, Anchorage, AK 99501. Telephone: (907) 271–1414. Email: *scabana@denali.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Denali Commission's mission is to partner with tribal, federal, state, and local governments and collaborate with all Alaskans to improve the effectiveness and efficiency of government services, to build and ensure the operation and maintenance of Alaska's basic infrastructure, and to develop a well-trained labor force employed in a diversified and sustainable economy.

By creating the Commission, Congress mandated that all parties involved partner together to find new and innovative solutions to the unique infrastructure and economic development challenges in America's most remote communities. Consistent with its statutory mission, in September of 2015 President Obama designated the Commission as the lead federal agency for coordinating federal efforts to mitigate the impacts of erosion, flooding and permafrost degradation in rural Alaska. The primary goal is to build climate resilience with respect to infrastructure in environmentally threatened communities.

Pursuant to the Act, the Commission determines its own basic operating principles and funding criteria on an annual federal fiscal year (October 1 to September 30) basis. The Commission outlines these priorities and funding recommendations in an annual Work Plan. The FY 2017 Work Plan was developed in the following manner.

- A workgroup comprised of Denali Commissioners and Commission staff developed a preliminary draft Work Plan.
- The preliminary draft Work Plan was published on *www.denali.gov* for review by the public in advance of public testimony.
- A public hearing was held to record public comments and recommendations on the preliminary draft Work Plan.
- Written comments on the preliminary draft Work Plan were accepted for another two weeks after the public hearing.
- All public hearing comments and written comments were provided to Commissioners for their review and consideration.
- Commissioners discussed the preliminary draft Work Plan in a public meeting and then voted on the Work Plan during the meeting.
- The Commissioners forwarded their recommended Work Plan to the Federal Co-Chair, who then prepared the draft Work Plan for publication in the **Federal Register** providing a 30-day period for public review and written comment. During this time, the draft Work Plan will also be disseminated to Commission program partners including, but not limited to, the Bureau of Indian Affairs (BIA), the Economic Development Administration (EDA), Department of Agriculture—Rural Utilities Service (USDA/RUS), and the State of Alaska.
- At the conclusion of the **Federal Register** Public comment period Commission staff provides the Federal Co-Chair with a summary of public comments and recommendations, if any, on the draft Work Plan.
- If no revisions are made to the draft, the Federal Co-Chair provides notice of approval of the Work Plan to the Commissioners, and forwards the Work Plan to the Secretary of Commerce for approval; or, if there are revisions the Federal Co-Chair provides notice of modifications to the Commissioners for theirconsideration and approval, and upon receipt of approval from Commissioners, forwards the Work Plan to the Secretary of Commerce for approval.
- The Secretary of Commerce approves the Work Plan.
- The Federal Co-Chair then approves grants and contracts based upon the approved Work Plan.

FY 2017 Appropriations Summary

The Commission has historically received federal funding from several sources. These fund sources are governed by the following general principles:

- In FY 2017 no project specific direction was provided by Congress.
- The Energy and Water Appropriation (*i.e.* "discretionary" or

“base” funding) is eligible for use in all programs.

- Certain appropriations are restricted in their usage. Where restrictions apply, the funds may be used only for specific program purposes.
- Final appropriation funds received may be reduced due to Congressional action, rescissions by the Office of Management and Budget (OMB), and other federal agency action.
- All Energy and Water Appropriation and Trans-Alaska Pipeline Liability (TAPL) funds, including operating funds, identified in the Work Plan, are “up to” amounts, and may be reassigned to other programs included in the current year work plan, if they are not fully expended in a program component area or a specific project.
- The proposed FY 2017 Work Plan is based upon the funds allocated to the Commission in Senate appropriation bill S.2804 of $15,000,000.

Approximately $3,000,000 of the $15,000,000 was allocated to administrative expenses and non-project program support leaving $12,000,000 available for program activities. The Commission anticipates TAPL funds of $3,600,000 will be allocated to the Commission with $200,000 of that amount being utilized for administrative expenses and non-project program support leaving $3,400,000 available for program activities.

DENALI COMMISSION FY 2017 FUNDING SUMMARY

Source	Available for program activities
Energy & Water Funds	
FY 2017 Appropriation [a]	$12,000,000
Subtotal	12,000,000
TAPL Funds	
FY 2017 Annual Allocation [b]	3,400,000
Subtotal	3,400,000
Grand Total	15,400,000

Notes:

a. Estimated FY 2017 program funds based on S.2804 Appropriations Bill; if the final Base appropriation is less than the amount in S.2804, the Federal Co-Chair shall reduce investments in the Energy Program to balance the FY 2017 Work Plan.

b. Estimated FY 2017 program funds based on discussions with OMB.

DENALI COMMISSION FY 2017 WORK PLAN

Program and type of investment	Energy and water funds	TAPL funds	Total
Energy			
Diesel Power Plants	$5,800,000		$5,800,000
Interties			
Wind/Microgrids			
Hydro, Biomass, Geothermal & Other Renewables			
Hydrokinetics & Others Emerging Technologies			
Audits, Technical Assistance, & Community Energy Improvements	500,000		500,000
RPSU Maintenance & Improvements	500,000		500,000
Subtotal	6,800,000	$0	6,800,000
Bulk Fuel			
New/Refurbished Facilities and Maintenance & Improvement Projects		3,200,000	3,200,000
Improve Administrative and Operation & Maintenance Projects	200,000	200,000	200,000
Subtotal	200,000	3,400,000	3,600,000
Environmentally Threatened Communities			
Mertarvik	1,500,000		1,500,000
Shaktoolik	500,000		500,000
Shishmaref	500,000		500,000
Kivalina	500,000		500,000
27 Other Communities in 2009 GAO Report	1,000,000		1,000,000
Program Development	1,000,000		1,000,000
Subtotal	5,000,000	0	5,000,000
Grand Total	12,000,000	3,400,000	15,400,000

Energy and Bulk Fuel Programs

FY 2017 Denali Commission investments in Energy and Bulk Fuel will include:

- Remote Power System Upgrade (RPSU) projects at locations selected based on need in consultation with the Alaska Energy Authority (AEA) and Alaska Village Electric Cooperative (AVEC).
- Bulk Fuel Upgrade (BFU) projects at locations selected based on need in consultation with AEA and AVEC.
- Rural power system and bulk fuel facility Maintenance and Improvement (M&I) projects at locations selected based on need in consultation with AEA and AVEC.
- Continued support of the rural power system and bulk fuel facility operator training programs managed by AEA.
- Continued support of initiatives at the State of Alaska Department of Community and Regional Affairs (DCRA) and the Alaska Community Foundation (ACF) to improve the administrative capacity related to operating bulk fuel facilities in rural Alaska.
- Continued support of the Sanitation Energy Efficiency Program at the Alaska Native Tribal Health Consortium (ANTHC).

Environmentally Threatened Communities Program

In order to fulfill its role as lead federal coordinating agency the Commission staff, in consultation with State, Federal, and other partners, and the referenced communities in particular, proposes the following investments in support of the new Environmentally Threatened Communities (ETC) Program. United States Government Accountability Office (GAO) Report 09–551 (*http://www.gao.gov/products/GAO-09-551*) was instrumental in charting prospective Commission investments.

Mertarvik

The community of Newtok has initiated its relocation to Mertarvik and has started building infrastructure at Mertarvik. The Commission funds summarized above will be used for the following activities:

- Continued support for the existing Community Relocation Coordinator.
- Continued support for professional project management services.
- Match/gap funds for on-going relocation activities.

Shaktoolik

The community of Shaktoolik has decided to protect the community in place for now. The Commission funds summarized above will be used for the following activities:

- Continued support for the existing Community Relocation Coordinator.
- Design of protect in place projects.
- Design and procure household and community emergency kits.
- Match/gap funds for other related activities.

Shishmaref

Shishmaref is considering relocation but has not yet selected a new site. The Commission funds summarized above will be used for the following activities:

- Continued support for the existing Community Relocation Coordinator
- Design of protect in place projects
- Design and procure household and community emergency kits
- Match/gap funds for other related activities

Kivalina

Kivalina is considering relocation and has selected a site for a new school. The Commission funds summarized above will be used for the following activities:

- Continued support for the existing Community Relocation Coordinator
- Design of protect in place projects
- Design and procure household and community emergency kits
- Match/gap funds for other related activities

Other Communities in the 2009 GAO Report

The Commission funds summarized above will be used for the following activities in support of the 27 other communities in GAO Report 09–551:

- Design of site specific projects based on existing Federal Emergency Management Administration approved Hazard Mitigation Plans and Small Community Emergency Response Plans

Program Development

The Commission intends to make $1,000,000 available for general ETC program development initiatives such as the following.

- Continued support of a fund that compliments other state and federal agencies responding to ETC related disasters
- Continued support of an ETC Grant Writing Center of Excellence being established at the Alaska Native Tribal Health Consortium
- Design of a prototype community shelter that can be site adapted to Shaktoolik, Shishmaref and Kivalina
- Analysis of existing erosion, permafrost degradation and flood data to quantify threats to infrastructure related to climate change
- ETC related outreach travel and partner support

Joel Neimeyer,

Federal Co-Chair.

[FR Doc. 2016–22704 Filed 9–20–16; 8:45 am]

BILLING CODE 3300–01–P

DEPARTMENT OF EDUCATION

Authorization of Subgrants for the Disability Innovation Fund—Automated Personalization Computing Project

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

[Catalog of Federal Domestic Assistance Number: 84.421A]

SUMMARY: This notice authorizes the use of subgrants with Disability Innovation Fund—Automated Personalization Computing (APC) Project funds awarded to the Board of Regents of the University of Wisconsin System under CFDA number 84.421A, as provided by the Consolidated Appropriations Act, 2014, for the purpose of carrying out its proposed activities to implement a demonstration of automated personalization computing for individuals with disabilities.

DATES: September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Douglas Zhu, U.S. Department of Education, Rehabilitation Services Administration, 550 12th Street SW., Room 5048, Potomac Center Plaza, 20202–5076. Telephone: (202) 245–6037 or by email: *Douglas.Zhu@ed.gov.*

If you use a telecommunications device for the deaf or a text telephone, you may call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Purpose of Program: The purpose of the Disability Innovation Fund is to support innovative activities aimed at improving the outcomes of "individuals with disabilities," as defined in section 7(20)(B) of the Rehabilitation Act of 1973, as amended.

Under this authority, the Department has entered into a cooperative agreement with the grantee to implement the Disability Innovation Fund—Automated Personalization Computing Project (APCP). This project is designed to improve outcomes for individuals with disabilities by increasing access to information and communication technologies through automatic personalization of needed assistive technology.

Program Authority: The Consolidated Appropriations Act, 2014 (Pub. L. 113–76).

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, and 99. (b) The OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The priorities and requirements in the notice inviting applications for this program, published July 23, 2015, in the **Federal Register** (80 FR 43763).

Eligible Entities for Subgrants: A State or public or non-profit agency or organization, including Indian tribes and institutions of higher education.

Discussion: Recognizing that the APC project will need to involve coordination among several different sectors, including cloud or other technology platform providers, assistive technology researchers and manufacturers, and disability advocacy organizations, the Department has required that the grantee set up a partnership involving highly experienced public and private entities. The subgranting authority will allow the grantee to tap unique talent sources with the technical expertise to carry out the activities of the project. Examples of proposed activities to be carried out by these subgrantees could include but are not limited to: Development of accessibility infrastructure for auto-personalization; pilot test coordination (America's Job Centers, employers, and educational institutions); and metrics development, collection, and analysis. Pursuant to 34 CFR 75.708(b)(2), the grantee may make subgrants to eligible entities that have already been identified in its approved application or to other eligible entities that are selected through a competitive process set out in subgranting procedures established by the grantee.

Requirements: If the grantee uses this subgranting authority, the subgrants must be used to directly carry out project activities described in the grantee's application. The grantee must ensure that the subgrants are awarded on the basis of an approved budget that is consistent with the grantee's approved application and all applicable Federal statutory, regulatory, and other requirements. The grantee must also ensure that every subgrant includes any conditions required by Federal statutes and Executive orders and their implementing regulations. Finally, the grantee must ensure that subgrantees are aware of requirements imposed by Federal statutes and regulations, including the Federal anti-discrimination laws enforced by the Department, which are set out at 34 CFR 75.500.

Note: This notice does not solicit applications. The Disability Innovation Fund—Automatic Personalization Computing Project (CFDA number 84.421A) has been awarded to the Board of Regents of the University of Wisconsin System.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.*, braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: September 16, 2016.

Sue Swenson,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2016–22774 Filed 9–20–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Membership of the Performance Review Board

AGENCY: Office of Management, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary publishes a list of persons who may be named to serve on the Performance Review Board that oversees the evaluation of performance appraisals for Senior Executive Service members of the Department.

DATES: *Effective Date:* September 21, 2016.

SUPPLEMENTARY INFORMATION:

Membership

Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board members be published in the **Federal Register**. The following persons may be named to serve on the Performance Review Board:

ANDERSON, MARGO K.
ANTHONY, PERRY E.
APPEL, CHARLES J.
ASHLEY, CAROL
BAKER, JEFFREY S.
BATTLE, SANDRA G.
BERGSTROM, PETER
BETKA, SUE E.
BUCK, RUTHANNE L.
BYRD-JOHNSON, LINDA
CANELLOS, ERNEST C.
CARR, PEGGY G.
CARTER, DENISE L.
CHANG, LISA
CHAPMAN, CHRISTOPHER
CHAVEZ, ANTHONY
CHISM, MONIQUE M.
COLE, KEIA
CONATY, JOSEPH C.
CORDES, WILLIAM
CUFFEE-GRAVES, CASSANDRA L.
DABBY, NADYA C.
DIPAOLO, JOHN K.
ELIADIS, PAMELA D.
ELLIS, KATHRYN A.
FEELY, HARRY M.
FORD, KIM
GALANTER, SETH M.
GIL, LIBIA S.
GINNS, LAURA
GRAY, JASON
GREEN, BIANCA
HAIRFIELD, JAMES M.
HALL, LINDA W.
HUNTER REED, KIM
HURT, JOHN W. III
JENKINS, HAROLD B.
KEAN, LARRY G.
KIM, ROBERT
KOEPPEL, DENNIS P.
LEHRICH, MATTHEW
LUCAS, RICHARD J.
LUCZAK, RONALD J.
MAESTRI, PHILIP A.
MAHAFFIE, LYNN B.
MALAWER, HILARY
MCFADDEN, ELIZABETH A.
MCINTOSH, AMY B.
MCLAUGHLIN, MAUREEN A.
MILLER, DANIEL
MOORE, KENNETH
NAVARRO, ERICA
PENDLETON, AUDREY J.

PEPIN, ANDREW, J.
RIDDLE, PAUL N.
ROBISON, GREGORY
ROSENFELT, PHILIP H.
RYDER, RUTH E.
SANTY, ROSS JR.
SASSER, TRACEY L.
SHILLING, RUSSELL D.
SIMPSON, DANIEL
SKELLY, THOMAS P.
SOLTIS, TIMOTHY F.
SOUTH, JOSEPH
STANTON, CRAIG
STRACKE, LINDA A.
STYLES, KATHLEEN M.
SWENSON, SUE ELLEN
THOMAS, MILTON L. JR.
UVIN, JOHAN E.
VADEHRA, EMMA
WASHINGTON, MARK
WHALEN, ANTONIA
WILBANKS, LINDA R.
WILLS, RANDOLPH E.
WOOD, GARY H.
WOOD, HAMILTON E. JR.

FOR FURTHER INFORMATION CONTACT: Valarie Barclay, Director, Executive Resources Division, Office of Human Resources, Office of Management, U.S. Department of Education, 400 Maryland Avenue SW., Room 2C150, LBJ, Washington, DC 20202–4573. Telephone: (202) 453–5918.

If you use a telecommunications device for the deaf (TDD), or text telephone (TTY), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Accessible Format: Individuals with disabilities may obtain this document in an alternative format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT.**

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: September 16, 2016.

John King,

Secretary of Education.

[FR Doc. 2016–22766 Filed 9–20–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[Certification Notice—243]

Notice of Filing of Self-Certification of Coal Capability Under the Powerplant and Industrial Fuel Use Act

AGENCY: Office of Electricity Delivery and Energy Reliability, DOE.

ACTION: Notice of filing.

SUMMARY: On September 7, 2016, Indeck Niles, LLC, as owner and operator of a new baseload electric generating powerplant, submitted a coal capability self-certification to the Department of Energy (DOE), pursuant to the Powerplant and Industrial Fuel Use Act of 1978 (FUA).

ADDRESSES: Copies of coal capability self-certification filings are available for public inspection, upon request, in the Office of Electricity Delivery and Energy Reliability, Mail Code OE–20, Room 8G–024, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Christopher Lawrence at (202) 586–5260.

SUPPLEMENTARY INFORMATION: The filing is pursuant to § 201(d) of the Powerplant and Industrial Fuel Use Act of 1978 (FUA), as amended, and DOE regulations in 10 CFR 501.60, 61. The FUA and regulations thereunder require DOE to publish a notice of filing of self-certification in the **Federal Register**. 42 U.S.C. 8311(d) and 10 CFR 501.61(c). Title II of FUA, as amended (42 U.S.C. 8301 *et seq.*), provides that no new base load electric powerplant may be constructed or operated without the capability to use coal or another alternate fuel as a primary energy source. Pursuant to the FUA, in order to meet the requirement of coal capability, the owner or operator of such a facility proposing to use natural gas or petroleum as its primary energy source shall certify to the Secretary of Energy (Secretary) prior to construction, or prior to operation as a base load electric powerplant, that such powerplant has the capability to use coal or another alternate fuel. Such certification establishes compliance with FUA section 201(a) as of the date it is filed with the Secretary. 42 U.S.C. 8311.

The following owner of a proposed new baseload electric generating powerplant has filed a self-certification of coal-capability with DOE pursuant to FUA section 201(d) and in accordance with DOE regulations in 10 CFR 501.60, 61:

Owner: Indeck Niles, LLC
Capacity: 1000 megawatts (MW)
Plant Location: Niles City Industrial Park, Niles, MI.
In-Service Date: May 2020

Issued in Washington, DC, on September 14, 2016.

Christopher Lawrence,

Electricity Policy Analyst, Office of Electricity Delivery and Energy Reliability.

[FR Doc. 2016–22627 Filed 9–20–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Orders Granting Authority To Import and Export Natural Gas, To Import and Export Liquefied Natural Gas, and To Vacate Prior Authorization, During August 2016

	FE Docket Nos.
CLEAN ENERGY	16–92–LNG
RIO GRANDE LNG, LLC	15–190–LNG
TRAILSTONE NA LOGISTICS, LLC	16–96–NG
COKINOS ENERGY CORPORATION	16–97–NG
CENTRAL VALLE HERMOSO, S.A. DE C.V	16–95–NG
ST. CLAIR POWER L.P	16–94–NG
PETROCHINA INTERNATIONAL (AMERICA), INC	16–93–NG
BIOURJA TRADING, LLC	16–91–NG
TWIN EAGLE RESOURCE MANAGEMENT, LLC	16–100–NG
AMERICAN LNG MARKETING LLC	16–33–LNG
ENBRIDGE GAS NEW BRUNSWICK LIMITED PARTNERCHIP	16–99–NG
EXELON GENERATION COMPANY, LLC	16–104–NG

	FE Docket Nos.
EXGEN ENERGY, S.R.L	16–105–NG
BOISE WHITE PAPER, L.L.C	16–106–NG
BIOURJA POWER, LLC	16–90–NG
MERRILL LYNCH COMMODITIES, INC	16–101–NG
MERRICL LYNCH COMMODITIES CANADA, ULC	16–102–NG 14–198–NG

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during August 2016, it issued orders granting authority to import and export natural gas, to import and export liquefied natural gas (LNG), and to vacate prior authority. These orders are summarized in the attached appendix and may be found on the FE Web site at *http://energy.gov/fe/listing-doefe-authorizationsorders-issued-2016.*

They are also available for inspection and copying in the U.S. Department of Energy (FE–34), Division of Natural Gas Regulation, Office of Regulation and International Engagement, Office of Fossil Energy, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on September 14, 2016.

John A. Anderson,

Director, Office of Regulation and International Engagement, Office of Oil and Natural Gas.

APPENDIX

DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS

3865	08/22/16	16–02–LNG	Clean Energy	Order 3865 granting blanket authority to import/export LNG from/to Free Trade Agreement Nations by truck, rail, barge, or other waterborne vessel.
3869	08/17/16	15–190–LNG	Rio Grande LNG, LLC	Order 3869 granting long-term Multi-contract authority to export LNG by vessel from the Proposed Rio Grande LNG Terminal in Brownsville, Texas, to Free Trade Agreement Nations.
3870	08/09/16	16–96–NG	Trailstone NA Logistics, LLC	Order 3870 granting blanket authority to import/export natural gas from/to Canada/Mexico.
3871	08/09/16	16–97–NG	Cokinos Energy Corporation	Order 3871 granting blanket authority to export natural gas to Mexico.
3872	08/09/16	16–95–NG	Central Valle Hermoso, S.A. de C.V	Order 3872 granting blanket authority to import/export natural gas from/to Mexico.
3873	08/09/16	16–94–NG	St. Clair Power L.P	Order 3873 granting blanket authority to import/export natural gas from/to Canada.
3874	08/09/16	16–93–NG	Petrochina International (America), Inc.	Order 3874 granting blanket authority to import/export natural gas from/to Canada/Mexico.
3875	08/19/16	16–91–NG	BioUrja Trading, LLC	Order 3875 granting blanket authority to import/export natural gas from/to Canada/Mexico.
3876	08/19/16	16–100–NG	Twin Eagle Resource Management, LLC.	Order 3876 granting blanket authority to import/export natural gas from/to Canada and to export natural gas to Mexico.
3877	08/24/16	16–33–LNG	American LNG Marketing LLC	Order 3877 granting blanket authority to export LNG in ISO Containers loaded at the Hialeah facility near Medley, Florida, and exported by vessel.
3878	08/25/16	16–99–NG	Enbridge Gas New Brunswick Limited Partnership.	Order 3878 granting blanket authority to import/export natural gas from/to Canada.
3879	08/25/16	16–104–NG	Exelon Generation Company, LLC	Order 3879 granting blanket authority to import/export natural gas from/to Mexico.
3880	08/25/16	16–105–NG	ExGen Energy, S.R.L	Order 3880 granting blanket authority to import/export natural gas from/to Canada.
3881	08/25/16	16–106–NG	Boise White Paper, L.L.C	Order 3881 granting blanket authority to import natural gas from Canada.
3882	08/30/16	16–90–NG	BioUrja Power, LLC	Order 3882 granting blanket authority to import/export natural gas from/to Canada/Mexico.
3883	08/30/16	16–101–NG	Merrill Lynch Commodities, Inc	Order 3883 granting blanket authority to import/export natural gas from/to Canada/Mexico.
3884	08/30/16	16–102–NG/14–198–NG	Merrill Lynch Commodities Canada, ULC.	Order 3884 granting blanket authority to export natural gas to Canada and vacating prior authorization.

[FR Doc. 2016–22750 Filed 9–20–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2578–000]

North Lancaster Ranch LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of North Lancaster Ranch LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 3, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 13, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–22644 Filed 9–20–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–181–000.
Applicants: Jericho Rise Wind Farm LLC.
Description: Application for Authorization for Disposition of Jurisdictional Facilities and Request for Expedited Action of Jericho Rise Wind Farm LLC.
Filed Date: 9/13/16.
Accession Number: 20160913–5448.
Comments Due: 5 p.m. ET 10/4/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2980–007; ER10–2983–007.
Applicants: Castleton Power, LLC, Castleton Energy Services, LLC.
Description: Supplement to August 19, 2016 Notice of Non-Material Change in Status of Castleton Power, LLC, et al.
Filed Date: 9/13/16.
Accession Number: 20160913–5444.
Comments Due: 5 p.m. ET 10/4/16.

Docket Numbers: ER13–102–011.
Applicants: New York Independent System Operator, Inc.
Description: Compliance filing: Compliance with 12/23/15 Order 1000 directives to be effective 4/1/2016.
Filed Date: 9/13/16.
Accession Number: 20160913–5407.
Comments Due: 5 p.m. ET 10/4/16.

Docket Numbers: ER16–1758–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2016–09–14_Compliance re Filing to revise SSR tariff provisions to be effective 8/22/2016.
Filed Date: 9/14/16.
Accession Number: 20160914–5026.
Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: ER16–2584–000.
Applicants: RE Astoria LLC.
Description: Section 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing for Astoria to be effective 9/15/2016.
Filed Date: 9/14/16.
Accession Number: 20160914–5036.
Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: ER16–2585–000.
Applicants: RE Astoria 2 LLC.
Description: Section 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing Astoria 2 to be effective 9/15/2016.
Filed Date: 9/14/16.
Accession Number: 20160914–5037.
Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: ER16–2586–000.
Applicants: RE Mustang LLC.
Description: Section 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing Mustang to be effective 9/15/2016.
Filed Date: 9/14/16.
Accession Number: 20160914–5042.
Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: ER16–2587–000.
Applicants: RE Mustang 3 LLC.
Description: Section 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing Mustang 3 to be effective 9/15/2016.
Filed Date: 9/14/16.
Accession Number: 20160914–5043.
Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: ER16–2588–000.
Applicants: RE Mustang 4 LLC.
Description: Section 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing Mustang 4 to be effective 9/15/2016.
Filed Date: 9/14/16.
Accession Number: 20160914–5044.
Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: ER16–2589–000.
Applicants: RE Barren Ridge 1 LLC.
Description: Section 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing Barren Ridge to be effective 9/15/2016.
Filed Date: 9/14/16.
Accession Number: 20160914–5045.
Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: ER16–2590–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Section 205(d) Rate Filing: 2016–09–14_Revisions to Coordination Agreement between MISO and IESO to be effective 7/22/2016.
Filed Date: 9/14/16.
Accession Number: 20160914–5063.
Comments Due: 5 p.m. ET 10/5/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 14, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–22645 Filed 9–20–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG16–149–000.
Applicants: North Lancaster Ranch LLC.
Description: North Lancaster Ranch LLC Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 9/12/16.
Accession Number: 20160912–5825.
Comments Due: 5 p.m. ET 10/3/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–2231–000.
Applicants: NorthWestern Corporation.
Description: Report Filing: Supplemental Information re Revisions to Market-Based Rate Tariff to be effective N/A.
Filed Date: 9/12/16.
Accession Number: 20160912–5903.
Comments Due: 5 p.m. ET 10/3/16.

Docket Numbers: ER16–2492–001.
Applicants: Phoenix Energy New England, LLC.
Description: Tariff Amendment: Amended MBR Tariff Filing to be effective 9/26/2016.
Filed Date: 9/13/16.
Accession Number: 20160913–5391.
Comments Due: 5 p.m. ET 10/4/16.

Docket Numbers: ER16–2527–001.
Applicants: Caprock Solar I LLC.
Description: Tariff Amendment: Supplement to MBR Filing to be effective 11/1/2016.
Filed Date: 9/13/16.
Accession Number: 20160913–5326.
Comments Due: 5 p.m. ET 10/4/16.

Docket Numbers: ER16–2581–000.
Applicants: Western Antelope Dry Ranch LLC.
Description: Baseline eTariff Filing: Western Antelope Dry Ranch LLC SFA to be effective 9/15/2016.
Filed Date: 9/13/16.
Accession Number: 20160913–5015.
Comments Due: 5 p.m. ET 10/4/16.

Docket Numbers: ER16–2582–000.
Applicants: North Lancaster Ranch LLC.
Description: Baseline eTariff Filing: North Lancaster Ranch LLC SFA to be effective 10/1/2016.
Filed Date: 9/13/16.
Accession Number: 20160913–5016.
Comments Due: 5 p.m. ET 10/4/16.

Docket Numbers: ER16–2583–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Section 205(d) Rate Filing: 2016–09–13_SA 1563 NIPSCO-Hoosier Wind Project GIA (N001/J431) to be effective 9/14/2016.
Filed Date: 9/13/16.
Accession Number: 20160913–5327.
Comments Due: 5 p.m. ET 10/4/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 13, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–22640 Filed 9–20–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2506–000]

Oliver Wind III, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Oliver Wind III, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 3, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email

FERCOnlineSupport@ferc.gov. or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 12, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–22642 Filed 9–20–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–2577–000]

Lindahl Wind Project, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Lindahl Wind Project, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is October 3, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 13, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–22643 Filed 9–20–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–179–000.
Applicants: Solverde 1, LLC.
Description: Application for Authorization under Section 203 of the Federal Power Act, Request for Expedited Consideration and Confidential Treatment of Solverde 1, LLC.
Filed Date: 9/9/16.
Accession Number: 20160909–5415.
Comments Due: 5 p.m. ET 9/30/16.

Docket Numbers: EC16–180–000.
Applicants: Antelope DSR 1, LLC.
Description: Application for Authorization under Section 203 of the Federal Power Act, Request for Expedited Consideration and Confidential Treatment of Antelope DSR 1, LLC.
Filed Date: 9/9/16.
Accession Number: 20160909–5417.
Comments Due: 5 p.m. ET 9/30/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1651–003.
Applicants: Golden State Water Company.
Description: Supplement to June 28 2016 Updated Market Power Analysis of Golden State Water Company.
Filed Date: 9/9/16.
Accession Number: 20160909–5411.
Comments Due: 5 p.m. ET 11/8/16.

Docket Numbers: ER16–2044–000.
Applicants: Elk Hills Power, LLC.
Description: Supplement to June 28 2016 Updated Market Power Analysis for the Southwest Region of Elk Hills Power, LLC.
Filed Date: 9/9/16.
Accession Number: 20160909–5421.
Comments Due: 5 p.m. ET 11/8/16.

Docket Numbers: ER16–2577–000.
Applicants: Lindahl Wind Project, LLC.
Description: Baseline eTariff Filing: MBR Tariff to be effective 11/10/2016.
Filed Date: 9/12/16.
Accession Number: 20160912–5708.
Comments Due: 5 p.m. ET 10/3/16.

Docket Numbers: ER16–2578–000.
Applicants: North Lancaster Ranch LLC.
Description: Baseline eTariff Filing: North Lancaster Ranch LLC MBR Tariff to be effective 9/13/2016.
Filed Date: 9/12/16.
Accession Number: 20160912–5716.
Comments Due: 5 p.m. ET 10/3/16.

Docket Numbers: ER16–2579–000.
Applicants: American Electric Power Service Corporation, PJM Interconnection, L.L.C.
Description: Section 205(d) Rate Filing: AEP Submits 48th Revised Service Agreement No 1336 with Buckeye Power to be effective 8/11/2016.
Filed Date: 9/12/16.
Accession Number: 20160912–5848.
Comments Due: 5 p.m. ET 10/3/16.

Docket Numbers: ER16–2580–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Section 205(d) Rate Filing: 2016–09–12_Bi-Directional EARS Exemption Filing to be effective 11/12/2016.
Filed Date: 9/12/16.
Accession Number: 20160912–5876.
Comments Due: 5 p.m. ET 10/3/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 12, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–22639 Filed 9–20–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–341–001; ER16–343–001; ER16–498–001; ER16–499–001; ER16–500–001; ER16–645–001.

Applicants: RE Astoria LLC, RE Astoria 2 LLC, RE Mustang LLC, RE Mustang 3 LLC, RE Mustang 4 LLC, RE Barren Ridge 1 LLC.

Description: Supplement to June 28, 2016 Triennial Market Power Analysis for Southwest Region of the Recurrent MBR Sellers.

Filed Date: 9/14/16.

Accession Number: 20160914–5102.

Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: ER16–2591–000.

Applicants: Southern California Edison Company.

Description: Section 205(d) Rate Filing: GIA and Distribution Service Agreement Commerce Refuse to Energy Authority to be effective 1/1/2017.

Filed Date: 9/14/16.

Accession Number: 20160914–5077.

Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: ER16–2592–000.

Applicants: Southern California Edison Company.

Description: Section 205(d) Rate Filing: Amended SGIA with SS San Antonio West, LLC to be effective 11/15/2016.

Filed Date: 9/14/16.

Accession Number: 20160914–5094.

Comments Due: 5 p.m. ET 10/5/16.

Docket Numbers: ER16–2593–000.

Applicants: Land O'Lakes, Inc.

Description: Compliance filing: Land O Lakes Revised Tariff Filing to be effective 11/13/2016.

Filed Date: 9/14/16.

Accession Number: 20160914–5104.

Comments Due: 5 p.m. ET 10/5/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 14, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–22646 Filed 9–20–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR16–71–000.

Applicants: Columbia Gas of Ohio, Inc.

Description: Tariff filing per 284.123(b)(1)/.: COH August 29 2016 SOC to be effective 8/29/2016; Filing Type: 980.

Filed Date: 9/9/2016.

Accession Number: 201609095151.

Comments/Protests Due: 5 p.m. ET 9/30/16.

Docket Numbers: RP16–1234–000.

Applicants: Anadarko Energy Services Company.

Description: Petition for Temporary Waivers of Capacity Release Regulations and Policies, Request for Shortened Comment Period and Expedited Treatment of Anadarko Energy Services Company under RP16–1234.

Filed Date: 9/8/16.

Accession Number: 20160908–5232.

Comments Due: 5 p.m. ET 9/15/16.

Docket Numbers: RP16–1235–000.

Applicants: Equitrans, L.P.

Description: Section 4(d) Rate Filing: Assignment of Anja Resources Agreement to TAPO Energy to be effective 9/1/2016.

Filed Date: 9/9/16.

Accession Number: 20160909–5174.

Comments Due: 5 p.m. ET 9/21/16.

Docket Numbers: RP16–1236–000.

Applicants: Southern Star Central Gas Pipeline, Inc.

Description: Section 4(d) Rate Filing: LINN—Satanta to Jayhawk Filing to be effective 9/20/2016.

Filed Date: 9/9/16.

Accession Number: 20160909–5196.

Comments Due: 5 p.m. ET 9/21/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 12, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–22641 Filed 9–20–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPA–2007–0042; FRL–9950–64–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; National Oil and Hazardous Substances Pollution Contingency Plan Regulation (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), "National Oil and Hazardous Substances Pollution Contingency Plan Regulation, subpart J (40 CFR 300.900) (Renewal)" (EPA ICR No. 1664.11, OMB Control No. 2050–0141) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2016. Public comments were previously requested via the **Federal Register** (81 FR 16174) on March 25, 2016 during a

60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 21, 2016.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OPA–2007–0042, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *Docket.rcra@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Leigh DeHaven, Office of Emergency Management, Regulations Implementation Division (5104A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–1974; email address: *DeHaven.Leigh@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This renewal supports activities to implement the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), subpart J (40 CFR 300.900, "Use of Dispersants and Other Chemicals"). The use of bioremediation agents, dispersants, surface washing agents, surface collecting agents and miscellaneous oil spill control agents in response to oil spills in U.S. waters or adjoining shorelines is governed by subpart J of the NCP regulation (40 CFR 300.900). Subpart J requirements include criteria for listing oil spill mitigating agents on the NCP Product Schedule. EPA's regulation, which is codified at 40 CFR 300.00, requires that EPA prepare a schedule of "dispersants, other chemicals, and other spill mitigating devices and substances, if any, that may be used in carrying out the NCP." The Schedule is required by section 311(d)(2)(G) of the Clean Water Act (CWA), as amended by the Oil Pollution Act of 1990. The Schedule is used by Federal On-Scene Coordinators (FOSCs), Regional Response Teams (RRTs), and Area Planners to identify spill mitigating agents in preparation for and response to oil spills. Under subpart J, respondents who want to add a product to the Schedule must submit technical product data to EPA as stipulated in 40 CFR 300.915. Specifically, Subpart J requires the manufacturer to conduct specific toxicity and effectiveness tests and submit the corresponding technical product data along with other detailed information to EPA's Office of Emergency Management, Office of Land and Emergency Management.

Form Numbers: None.

Respondents/affected entities: Manufacturers of bioremediation agents, dispersants, surface collecting agents, surface washing agents, and other chemical agents.

Respondent's obligation to respond: Required to obtain or retain benefits (40 CFR 300.900).

Estimated number of respondents: 21.

Frequency of response: Once.

Total estimated burden: 315 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $89,590 (per year), which includes $72,450 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no change of hours in the total estimated respondent burden compared with the ICR currently approved by OMB. All regulatory requirements remain the same as in the previous ICRs for the 1994 subpart J Rule.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2016–22661 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9952–78–OECA]

National Environmental Justice Advisory Council; Notification of Public Meeting and Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), Public Law 92–463, the U.S. Environmental Protection Agency (EPA) hereby provides notice that the National Environmental Justice Advisory Council (NEJAC) will meet on the dates and times described below. All meetings are open to the public. Members of the public are encouraged to provide comments relevant to the specific issues being considered by the NEJAC. For additional information about registering to attend the meeting or to provide public comment, please see "REGISTRATION" under **SUPPLEMENTARY INFORMATION.** Due to a limited space, seating at the NEJAC meeting will be on a first-come, first served basis. Pre-registration is highly suggested.

DATES: The NEJAC will convene Wednesday, October 12, 2016 and Thursday, October 13, 2016, from 9:00 a.m. until 5:00 p.m. Eastern Time each day. The theme for this meeting will be a reflection on the past eight years of environmental justice at EPA. The discussion will focus on this administration's accomplishments, challenges and future of furthering environmental justice throughout the work at EPA. One public comment period relevant to the specific issues being considered by the NEJAC (see **SUPPLEMENTARY INFORMATION**) is scheduled for Wednesday, October 12, 2016, starting at 6:00 p.m. Eastern Time. Members of the public who wish to participate during the public comment period are highly encouraged to pre-register by 11:59 p.m. Eastern Time on Wednesday, October 5, 2016.

ADDRESSES: The NEJAC meeting will be held at U.S. EPA Headquarters One Potomac Yard South, 2777 S. Crystal Drive, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Questions or correspondence concerning the teleconference meeting should be directed to Karen L. Martin, U.S. Environmental Protection Agency, by mail at 1200 Pennsylvania Avenue NW. (MC2201A), Washington, DC 20460; by telephone at 202–564–0203; via email at *martin.karenl@epa.gov;* or by fax at 202–564–1624. Additional information about the NEJAC is available at: *www.epa.gov/environmentaljustice/nejac.*

SUPPLEMENTARY INFORMATION: The Charter of the NEJAC states that the advisory committee "will provide independent advice and recommendations to the Administrator about broad, crosscutting issues related to environmental justice. The NEJAC's efforts will include evaluation of a broad range of strategic, scientific, technological, regulatory, community engagement and economic issues related to environmental justice."

Registration

Registration for the October 12–13, 2016, public face-to-face meeting will be processed at *http://nejac-public-meeting-october-12th-13th-2016.eventbrite.com.* Pre-registration is highly suggested. Registration for the October 12–13, 2016, public meeting teleconference option will be processed at *http://nejac-public-teleconference-october-12th-13th-2016.eventbrite.com.* Pre-registration is required. Registration for the October 12–13, 2016, teleconference meeting closes at 11:59 p.m., Eastern Time on Wednesday, October 05, 2016. The deadline to sign up to speak during the public comment period, or to submit written public comments, is 11:59 p.m., Eastern Time on Wednesday, October 05, 2016. When registering, please provide your name, organization, city and state, email address, and telephone number for follow up. Please also indicate whether you would like to provide public comment during the meeting, and whether you are submitting written comments before the Wednesday, October 05, 2016, deadline.

A. Public Comment

Individuals or groups making remarks during the public comment period will be limited to seven (7) minutes. To accommodate the number of people who want to address the NEJAC, only one representative of a particular community, organization, or group will be allowed to speak. Written comments can also be submitted for the record. The suggested format for individuals providing public comments is as follows: Name of speaker; name of organization/community; city and state; and email address; brief description of the concern, and what you want the NEJAC to advise EPA to do. Written comments received by registration deadline, will be included in the materials distributed to the NEJAC prior to the teleconference. Written comments received after that time will be provided to the NEJAC as time allows. All written comments should be sent to Karen L. Martin, EPA, via email at *martin.karenl@epa.gov.*

B. Information About Services for Individuals With Disabilities or Requiring English Language Translation Assistance

For information about access or services for individuals requiring assistance, please contact Karen L. Martin, at (202) 564–0203 or via email at *martin.karenl@epa.gov.* To request special accommodations for a disability or other assistance, please submit your request at least seven (7) working days prior to the meeting, to give EPA sufficient time to process your request. All requests should be sent to the address, email, or phone/fax number listed in the **FOR FURTHER INFORMATION, CONTACT** section.

Dated: August 29, 2016.

Matthew Tejada,

Designated Federal Officer, National Environmental Justice Advisory Council.

[FR Doc. 2016–22772 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2006–0525; FRL–9950–78–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Registration of Fuels and Fuel Additives—Health-Effects Research Requirements for Manufacturers (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), "Registration of Fuels and Fuel Additives—Health-Effects Research Requirements for Manufacturers (Renewal)" (EPA ICR No. 1696.09, OMB Control No. 2060–0297) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2016. Public comments were previously requested via the **Federal Register** (81 FR 22080) on April 14, 2016 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection for information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 21, 2016.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2006–0525, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *a-and-r-docket@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: James W. Caldwell, Compliance Division, Office of Transportation and Air Quality, Mail Code 6405A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 343–9303; email address: *caldwell.jim@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* on in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: In accordance with the regulations at 40 CFR 79, Subparts A, B C, and D, Registration of Fuels and Fuel Additives, manufacturers (including importers) of motor-vehicle gasoline, motor-vehicle diesel fuel, and additives for those fuels are required to have these products registered by the EPA prior to their introduction into commerce. Registration involves providing a chemical description of the fuel or additive, and certain technical, marketing, and health-effects information. The development of health-effects data, as required by 40 CFR 79, Subpart F, is the subject of this ICR. The information collection requirements for Subparts A through D, and the supplemental notification requirements of Subpart F (indicating how the manufacturer will satisfy the health-effects data requirements) are covered by a separate ICR (EPA ICR No. 0309.14, OMB Control No. 2060–0150). The health-effects data will be used to determine if there are any products which have evaporative or combustion emissions that may pose an unreasonable risk to public health, thus meriting further investigation and potential regulation. This information is required for specific groups of fuels and additives as defined in the regulations.

Form numbers: None.

Respondents/affected entities: Manufacturers of motor-vehicle gasoline, motor-vehicle diesel fuel, and additives for those fuels.

Respondent's obligation to respond: Mandatory (40 CFR 79).

Estimated number of respondents: 2 (total).

Frequency of response: On occasion.

Total estimated burden: 17,600 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $2,053,800 (per year), includes $597,000 annualized capital or operation & maintenance costs.

Changes in estimates: There is a decrease of 1,600 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to a revision in the estimate for conducting the Tier 1 literature search.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2016–22662 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0452; FRL–9951–71]

Product Cancellation Order for Certain Pesticide Registrations and Amendment To Terminate a Certain Use

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations and amendment to terminate a certain use, voluntarily requested by the registrants and accepted by the Agency, of products containing the pesticides listed in Tables 1 and 2 of Unit II, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows a July 21, 2016 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 3 of Unit II. to voluntarily cancel these product registrations, as well as to amend a registration to terminate a certain use of a product. In the July 21, 2016 Notice, EPA indicated that it would issue an order implementing the cancellations and amendment to terminate a certain use, unless the Agency received substantive comments within the 30 day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests within this period. The Agency received one comment on the notice from a registrant to withdraw one cancellation request. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations and amendment to terminate a certain use. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Rachel Ricciardi, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0465; email address: *ricciardi.rachel@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0452, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. What action is the agency taking?

This notice announces EPA's order for the cancellation and amendment to terminate a certain use, as requested by registrants, of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Tables 1 and 2 of this unit. Also, the following registration numbers that were listed in the July 21, 2016 notice (81 FR 47381) (FRL–9948–85), have already been cancelled because the required maintenance fees were not paid and are therefore not listed in this notice: 211–40, 211–50, 875–194, 1022–592, 1043–19, 1043–77, 4313–93, 5736–61, 5736–104, 5736–105, 5736–106, 6198–11, 7405–39, 8155–12, 8155–17, 8155–19, 8155–22, 8155–23, 8155–24, 9886–2, 9886–4, 9886–10, 9886–12, 9886–16, 9886–17, 11668–10, 11668–13, 11694–88, 15136–10, 15300–8, 41550–1, 47033–12, 49827–2, 51219–1, 51219–3, 51219–4, 58044–3, 66243–3, 70627–10, 70627–21, 70627–55, 84398–1, and 86130–5.

TABLE 1—PRODUCT CANCELLATIONS

Registration No.	Product name	Active ingredient
498–197	Spray Disinfectant	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14); Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12); and Ethanol.

TABLE 1—PRODUCT CANCELLATIONS—Continued

Registration No.	Product name	Active ingredient
777–44	Lysol Deodorizing Cleaner	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
1258–1275	A-Breeze Solid PHMB	Poly(iminoimidocarbonyliminoimidocarbonyliminohexamethylene) hydrochloride.
1258–1277	Vantocil S Microbiocide	Poly(iminoimidocarbonyliminoimidocarbonyliminohexamethylene) hydrochloride.
1258–1325	Baquacide 795 Swimming Pool Algicide	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
1459–72	Bullen Ready To Use Disinfectant	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12) and Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14).
1677–205	A–215	Glutaraldehyde.
1677–206	A–245	Glutaraldehyde.
1839–85	Aerosol Surface Disinfectant	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12); Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14); and Isopropyl alcohol.
1839–102	CD 4.5 (D & F)	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
1839–112	PT 4.0 Pine Scent Disinfectant/Detergent.	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12); Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14); and Pine Oil.
1839–128	BTC 99	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
1839–138	10% BTC 99 Industrial Water Cooling Tower Algaecide.	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
1839–188	Aerosol SDAS	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12); Isopropyl alcohol; Triethylene glycol; and Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14).
2296–102	NAC Pine Odor Disinfectant	Pine oil and 2-Benzyl-4-chlorophenol.
2296–104	NACA Pine Oil Disinfectant	Pine oil.
2296–105	Pine-Act	Pine oil and 2-Benzyl-4-chlorophenol.
2296–112	Mint Quat	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
3573–69	Z–1	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
3573–74	Cougar	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride and Chlorhexidine diacetate.
3862–11	Pine Odor Disinfectant	Pine oil and Sodium 2-benzyl-4-chlorophenate.
3862–76	Lemon DS–32	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12) and Alkyl* dimethyl ethylbenzyl ammonium chloride *(50%C12, 30%C14, 17%C16, 3%C18).
4822–554	AD–SS–06	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
5741–16	PSQ Disinfectant Cleaner	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
5813–28	Pine-Sol	Pine oil.
5813–33	Clean-O-Pine Cone Concentrated Disinfectant.	Pine oil.
5813–36	Pine Sol Cleaner Disinfectant	Pine oil.
5813–41	Clorox Pine Oil	Pine oil.
5813–54	Pine-Sol Cleaner Disinfectant 1	Pine oil.
5813–56	Pine-Sol Cleaner Disinfectant 6	Pine oil.
5813–83	Clorox Losenip	Pine oil.
6243–3	Auto-chlor DS–33	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
6718–24	Amway Pursue Disinfectant Cleaner	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–18	Bardac-22	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–19	Bardac-20	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–28	Lonza Disinfectant Cleaner (19–A)	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–30	Lonza Mildew Preventative	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–41	Lonza Mildew Preventative B–20	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; and 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride.
6836–48	Bardac 2250–7.5	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–68	Bardac 20W	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; and 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride.
6836–74	Lonza Formulation S–39	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
6836–87	Lonza DC–102 Quaternary Pine Oil	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16); and Pine oil.
6836–89	205M Sanitizer	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
6836–108	Lonza Carpet Sanitizer CS–202	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).

TABLE 1—PRODUCT CANCELLATIONS—Continued

Registration No.	Product name	Active ingredient
6836–163	Bio-Quat 50–MAB	Alkyl* dimethyl ethyl ammonium bromide *(90% C14, 5% C16, 5% C12).
6836–167	Bio-Guard M–7 Disinfectant	Alkyl* dimethyl benzyl ammonium chloride *(58%C14, 28%C16, 14%C12).
6836–204	Lonza Formulation DC–110N	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–205	Lonza Formulation DC–108N	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–206	Lonza Formulation DC–109N	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–231	Jordaquat 358	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
6836–267	Lonza Formulation DCN 400–256	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–268	Lonza Formulation DCN 400–128	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
6836–269	Lonza Formulation DCN 400–64	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
7124–39	Pool Brite Winterizer	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12); Dialkyl* methyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12); and EDTA, copper salt.
7124–105	Poly Clear	Poly(iminoimidocarbonyliminoimidocarbonyliminohexamethylene) hydrochloride.
7364–37	Green Algae Treatment	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
9613–5	Crystal—Aqua Swimming Pool Algaecide.	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 25%C12, 15%C16).
9613–13	Bison SP–5 Swimming Pool Algaecide	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 25%C12, 15%C16).
9688–287	Chemsico Insecticide RTU LG	o-Phenylphenol, sodium salt and lambda-Cyhalothrin.
10088–101	Bafix Germicidal Spray and Wipe Bathroom Cleaner.	Alkyl* dimethyl ethylbenzyl ammonium chloride *(50%C12, 30%C14, 17%C16, 3%C18) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10088–102	Wint Mint Disinfectant	Alkyl* dimethyl ethylbenzyl ammonium chloride *(50%C12, 30%C14, 17%C16, 3%C18) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–20	Maquat LC–12S–10%	Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C18).
10324–39	Maquat MQ2525M–P40	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–49	Maquat LC12–50%	Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C8, C10, and C18).
10324–64	Maquat 3.8–MN	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–65	Maquat 80	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–68	Maquat TC76–50% P	Dialkyl* methyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–73	Maquat MQ615–CT	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–76	Maquat MC6025–10%	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 25%C12, 15%C16).
10324–77	Maquat 50–CT	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–78	Maquat 75	Dialkyl* methyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–79	Maquat 3.8–M	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–82	Maquat 1.8–M	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–83	Maquat 7.0–M	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–84	Maquat 2.5–M	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–86	Maquat 2.56–M	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16); and 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride.
10324–90	Maquat LC12S	Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C18).
10324–102	Maquat MQ2525M–10% S&W	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–109	Maquat 615–LR	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–118	Maquat 256 EBC	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).

Table 1—Product Cancellations—Continued

Registration No.	Product name	Active ingredient
10324–119	Maquat 128 EBC	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–120	Maquat 64 EBC	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–124	Pine Odor D-Synfect 7 Disinfectant Cleaner Deodorant.	Pine oil and Alkyl* dimethyl benzyl ammonium chloride *(58%C14, 28%C16, 14%C12).
10324–131	Maquat A	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–134	Maquat 256–1010N	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
10324–143	Maquat 10–B	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–144	Maquat 256 MN–FCS	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–146	Maquat 128–1010N	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
10324–147	Maquat 64–1010N	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
10324–163	Maquat 12 MN	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–168	Maquat 615 SRTU–200	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–170	Maquat 64–PDX	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–171	Maquat 128–PD–X	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–172	Maquat 128–X	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–173	Maquat 64–X	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–179	Maquat 32 MN–FCS	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–180	Maquat 64 MN–FCS	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–181	Maquat 128 MN–FCS	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–183	Maquat Deter Antimicrobial Agent	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–189	Maquat 21.3–NHQ	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride and Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16).
10324–190	Maquat 14.0–M	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16); 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; and 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride.
10324–191	Maquat 3.5–M	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16); 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; and 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride.
10324–192	Maquat 1.75–M	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16); 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; and 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride.
10324–193	Maquat LC12S–40%-LF	Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C18).
10324–202	Maquat 25.6–X	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) and Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
10324–204	Maquat LC12S–50% EUFC	Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C18).
10324–205	Maquat LC12S–10%FC	Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C18).
10324–213	Maquat 7.5–S	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16); 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; and 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride.
10324–215	Bol Maid	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16); 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; and Hydrochloric acid.
10324–216	Betco Pull	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16); and Hydrochloric acid.

TABLE 1—PRODUCT CANCELLATIONS—Continued

Registration No.	Product name	Active ingredient
11694–98	Medaphene Plus Disinfectant Deodorant	o-Phenylphenol and Ethanol.
39967–96	N–1386 Technical	Bis(trichloromethyl) sulfone.
39967–97	N–1386 Hexylene Glycol	Bis(trichloromethyl) sulfone.
39967–109	N–1386 PEG–EU 20	Bis(trichloromethyl) sulfone.
47371–23	FMB 210–15 Quat Concentrated Germicide.	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
47371–47	FMB 210–8 Quat	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
47371–52	HS–210 Mildew Preventative	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
47371–53	Formulation HS 210–15	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
47371–59	FMB 210–100 Quat Concentrated Germicide.	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
47371–71	Huntington FMB 302–8 Quat Concentrated Germicide.	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride; 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride; and 1-Octanaminium, N,N-dimethyl-N-octyl-, chloride.
47371–86	TB–A23 Disinfectant Bowl Cleaner	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride and Hydrochloric acid.
47371–87	TB–A32 Disinfectant Bowl Cleaner	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride and Hydrochloric acid.
53053–5	Envirosystems Bioshield 7200	1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride.
53053–6	Envirosystems Proshield 5000	1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride.
53053–7	Envirosystems Bioshield 75	1-Octadecanaminium, N,N-dimethyl-N-[3-(trihydroxysilyl)propyl], chloride.
53053–8	Envirosystems Proshield 5000D	1-Octadecanaminium, N,N-dimethyl-N-(3-(trimethoxysilyl)propyl)-, chloride.
55195–4	Coldcide 0.25% Disinfecting Wipes	o-Phenylphenol; 4-tert-Amylphenol; and Glutaraldehyde.
60061–78	NP–1 Plus Sapstain Control Chemical	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride and Carbamic acid, butyl-, 3-iodo-2-propynyl ester.
67619–15	Needle	Pine oil.
67619–19	Snip	Pine oil.
70627–3	NADBC–101	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12) and Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14).
74655–6	Spectrum RX–38	Bis(trichloromethyl) sulfone and Methylene bis(thiocyanate).

TABLE 2—PRODUCT REGISTRATION AMENDMENT TO TERMINATE A CERTAIN USE

Registration No.	Product name	Active ingredient	Use deleted
39967–107	N–2000 Antimicrobial	Dodecylguanidine hydrochloride	Disposable diapers.

Table 3 of this unit includes the names and addresses of record for all registrants of the products in Tables 1 and 2 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Tables 1 and 2 of this unit.

TABLE 3—REGISTRANTS OF CANCELLED AND AMENDED REGISTRATION

EPA company No.	Company name and address
498	Chase Products Co., P.O. Box 70, Maywood, IL 60153.
777	Reckitt Benckiser LLC., 399 Interpace Parkway, Parsippany, NJ 07054.
1258	Arch Chemicals, Inc., 1200 Bluegrass Lakes Parkway, Alpharetta, GA 30004.
1459	The Bullen Companies, 1640 Delmar Drive, P.O. Box 37, Folcroft, PA 19032.
1677	Ecolab, Inc., 370 North Wabasha Street, St. Paul, MN 55102.
1839	Stepan Company, 22 W. Frontage Road, Northfield, IL 60093.
2296	National Chemical Laboratories, Inc., 401 N 10th Street, Philadelphia, PA 19123.
3573	The Proctor & Gamble Company, 5299 Spring Grove Avenue, F&HC PS&RA, Cincinnati, OH 45217.
3862	ABC Compounding Co, Inc, P.O. Box 16247, Atlanta, GA 30321.
4822	S.C. Johnson & Son Inc., 1525 Howe Street, Racine, WI 53403.
5741	Spartan Chemical Company, Inc., 1110 Spartan Drive, Maumee, OH 43537.
5813	Clorox Co., The, P.O. Box 493, Pleasanton, CA 94566.
6243	Auto-Chlor System, 746 Poplar Avenue, Memphis, TN 38105.
6718	Access Business Group International LLC, 7575 E. Fulton Road, MC 50–1A, Ada, MI 49355.
6836	Lonza Inc., 90 Boroline Road, Allendale, NJ 07401.
7124	Alden Leeds Inc, 55 Jacobus Avenue, South Kearny, NJ 07032.
7364	GLB Pool & Spa, 90 Boroline Road, Allendale, NJ 07401.
9613	Bison Labs Inc., 80 Leslie Street, Buffalo, NY 14211.
9688	Chemsico, P.O. Box 142642, St. Louis, MO 63114.
10088	Athea Laboratories Inc, P.O. Box 240014, Milwaukee, WI 53224.
10324	Mason Chemical Company, 723 W. Algonquin Road, Suite B, Arlington Heights, IL 60005.
11694	ITW Pro Brands, 805 East Old 56 Highway, Olathe, KS 66061.
39967	Lanxess Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275.
47371	H&S Chemicals Division, 90 Boroline Road, Allendale, NJ 07401.
53053	Indusco Ltd., 12733 Director's Loop, Woodbridge, VA 22192.
55195	Colcide, Inc., 12549 Ansin Circle Drive, Potomac, MD 20854.

TABLE 3—REGISTRANTS OF CANCELLED AND AMENDED REGISTRATION—Continued

EPA company No.	Company name and address
60061	Kop-Coat, Inc, 436 Seventh Avenue, Pittsburgh, PA 15219.
67619	Clorox Professional Products Co, C/O PS&RC, P.O. Box 493, Pleasanton, CA 94566.
70627	Diversey, Inc., 8310 16th Street, MS 707, Sturtevant, WI 53177.
74655	Solenis, LLC., 7910 Baymeadows Way, Suite 100, Jacksonville, FL 32256.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period, EPA received one comment. The comment was from Lonza Inc. on behalf of H&S Chemicals Division requesting that EPA Reg. No. 47371–58 be retained because the voluntary cancellation request was made in error. As a result of this comment, the Agency is retaining the registration of EPA Reg. No. 47371–58.

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)), EPA hereby approves the requested cancellations and amendment to terminate a certain use of dodecylguanidine hydrochloride (DGH) registration identified in Tables 1 and 2 of Unit II. Accordingly, the Agency orders that the product registrations identified in Tables 1 and 2 of Unit II. are hereby cancelled and amended to terminate the affected use. Any distribution, sale, or use of existing stocks of the products identified in Tables 1 and 2 of Unit II. in a manner inconsistent with any of the Provisions for Disposition of Existing Stocks set forth in Unit VI. will be considered a violation of FIFRA.

V. What is the agency's authority for taking this action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be cancelled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of July 21, 2016 (81 FR 47381) (FRL–9948–85). The comment period closed on August 22, 2016.

VI. Provisions for Disposition of Existing Stocks

EPA's existing stocks policy published in the **Federal Register** of June 26, 1991 (56 FR 29362) provides that: "If a registrant requests to voluntarily cancel a registration where the Agency has identified no particular risk concerns, the registrant has complied with all applicable conditions of reregistration, conditional registration, and data call ins, and the registration is not subject to a Registration Standard, Label Improvement Program, or reregistration decision, the Agency will generally permit a registrant to sell or distribute existing stocks for 1 year after the cancellation request was received. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted."

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action.

A. For Products 10324–64, 10324–73, 10324–79, 10324–82, 10324–83, 10324–84, 10324–86, 10324–109, 10324–131, 10324–134, 10324–144, 10324–146, 10324–147, 10324–163, 10324–168, 10324–179, 10324–180, 10324–181, 10324–189, 10324–190, 10324–191, 10324–192, 10324–213, 10324–215, and 10324–216

The registrant has requested to the Agency via letter to sell existing stocks for an 18-month period for products 10324–64, 10324–73, 10324–79, 10324–82, 10324–83, 10324–84, 10324–86, 10324–109, 10324–131, 10324–134, 10324–144, 10324–146, 10324–147, 10324–163, 10324–168, 10324–179, 10324–180, 10324–181, 10324–189, 10324–190, 10324–191, 10324–192, 10324–213, 10324–215, and 10324–216. The effective date of this cancellation is September 21, 2016. Because the Agency has identified no significant potential risk concerns associated with these pesticide products, upon cancellation, EPA anticipates allowing registrants to sell and distribute existing stocks of these products until March 21, 2018. Thereafter, registrants will be prohibited from selling or distributing the pesticides identified in Table 1 of Unit II., except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal. Persons other than registrants may sell, distribute, or use existing stocks of these products until existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

B. For All Other Products Identified in Table 1 and Table 2 of Unit II

Because the Agency has identified no significant potential risk concerns associated with these pesticide products, upon cancellation of the products or uses identified in Table 1 and Table 2 of Unit II., EPA anticipates allowing registrants to sell and distribute existing stocks of these products until September 21, 2017. Thereafter, registrants will be prohibited from selling or distributing the pesticides identified in Table 1 and Table 2 of Unit II., except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

Authority: 7 U.S.C. 136 *et seq.*

Dated: September 14, 2016.

Steve Knizner,

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 2016–22764 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2011–0901; FRL–952–70–OAR]

Proposed Information Collection Request; Comment Request; Prevention of Significant Deterioration and Nonattainment New Source Review (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an

information collection request (ICR), "Prevention of Significant Deterioration and Nonattainment New Source Review" (EPA ICR No. 1230.32, OMB Control No. 2060–0003) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through April 30, 2017. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before November 21, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2011–0901, to the *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Ben Garwood, Air Quality Policy Division, Office of Air Quality Planning and Standards, C504–03, U.S. Environmental Protection Agency, Research Triangle Park, NC 27709; telephone number: (919) 541–1358; fax number: (919) 541–5509; email address: *garwood.ben@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting document(s) which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is (202) 566–1744. For additional information about the EPA's public docket, visit *https://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical or other technological collection techniques or other forms of information technology, *e.g.,* allowing electronic submission of responses. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, the EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: This ICR is for activities related to the implementation of the EPA's New Source Review (NSR) program, for the time period between May 1, 2017, and April 30, 2020, and renews the previous ICR. Title I, part C of the Clean Air Act (CAA or the Act)—"Prevention of Significant Deterioration," and part D—"Plan Requirements for Nonattainment Areas," require all states to adopt preconstruction review programs for new or modified stationary sources of air pollution. In addition, the provisions of section 110 of the Act include a requirement for states to have a preconstruction review program to manage the emissions from the construction and modification of any stationary source of air pollution to assure that the National Ambient Air Quality Standards are achieved and maintained. Tribes may choose to develop implementation plans to address these requirements.

Implementing regulations for these three programs are promulgated at 40 CFR 49.101 through 49.105; 40 CFR 49.151 through 49.173; 40 CFR 51.160 through 51.166; 40 CFR part 51, Appendix S; and 40 CFR 52.21 and 52.24. In order to receive a construction permit for a major new source or major modification, the applicant must conduct the necessary research, perform the appropriate analyses and prepare the permit application with documentation to demonstrate that their project meets all applicable statutory and regulatory NSR requirements. Specific activities and requirements are listed and described in the Supporting Statement for the ICR.

State, local, tribal or federal reviewing authorities review permit applications and provide for public review of proposed projects and issue permits based on their consideration of all technical factors and public input. The EPA, more broadly, reviews a fraction of the total applications and audits the state and local programs for their effectiveness. Consequently, information prepared and submitted by sources is essential for sources to receive permits, and for federal, state, and local environmental agencies to adequately review the permit applications and thereby properly administer and manage the NSR programs.

Information that is collected is handled according to EPA's policies set forth in title 40, chapter 1, part 2, subpart B—Confidentiality of Business Information (*see* 40 CFR part 2). *See* also section 114(c) of the Act.

Form numbers: 5900–246, 5900–247, 5900–248, 5900–340, 5900–341, 5900–342, 5900–343, 5900–344, 5900–390, and 5900–391.

Respondents/affected entities: Entities potentially affected by this action are those which must apply for and obtain a preconstruction permit under part C or D or section 110(a)(2)(C) of title I of the Act. In addition, state, local and tribal reviewing authorities that must review permit applications and issue permits are affected entities.

Title: Prevention of Significant Deterioration and Nonattainment New Source Review (Renewal).

Respondent's obligation to respond: Mandatory [*see* 40 CFR part 49, subpart C; 40 CFR part 51, subpart I; 40 CFR part 52, subpart A; 40 CFR part 124, subparts A and C].

Estimated number of respondents: 73,762 (total); 73,639 industrial facilities and 123 state, local and tribal reviewing authorities.

Frequency of response: On occasion, as necessary.

Total estimated burden: 5,516,675 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $428,760,519 (per year). This includes $3,466,314 annually in outsourced start-up costs for preconstruction monitoring.

Changes in estimates: There is a decrease of 2,417,665 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease has two primary causes: (1) A significant decrease in the estimated number of industrial facilities subject to CAA title I, part C permitting as a result of the U.S. Supreme Court ruling in *Utility Air Regulatory Group (UARG)* v. *EPA* (134 S.Ct. 2427 (2014)); and (2) a significant decrease in the estimated number of permits and registrations on tribal lands based on the progress in, and experience with, implementing the tribal NSR program.

Dated: September 9, 2016.

Anna Marie Wood,

Director, Air Quality Policy Division, OAQPS.

[FR Doc. 2016–22770 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9945–98–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Oregon

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the State of Oregon's request to revise/modify certain of its EPA-authorized programs to allow electronic reporting.

DATES: EPA's approval is effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Karen Seeh, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 566–1175, *seeh.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On July 5, 2016, the Oregon Department of Environmental Quality (OR DEQ) submitted an application titled "National Network Discharge Monitoring Report System" for revisions/modifications to its EPA-approved programs under title 40 CFR to allow new electronic reporting. EPA reviewed OR DEQ's request to revise/modify its EPA-authorized programs and, based on this review, EPA determined that the application met the standards for approval of authorized program revisions/modifications set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Oregon's request to revise/modify its following EPA-authorized programs to allow electronic reporting under 40 CFR parts 122 and 403, is being published in the **Federal Register**:

Part 123—EPA Administered Permit Programs: The National Pollutant Discharge Elimination System; and

Part 403—General Pretreatment Regulations for Existing and New Sources of Pollution.

OR DEQ was notified of EPA's determination to approve its application with respect to the authorized programs listed above.

Matthew Leopard,

Director, Office of Information Collection.

[FR Doc. 2016–22671 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9926–08–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Alaska

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the State of Alaska's request to revise/modify its EPA Administered Permit Programs: The National Pollutant Discharge Elimination System EPA-authorized program to allow electronic reporting.

DATES: EPA's approval is effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Karen Seeh, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 566–1175, *seeh.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On August 8, 2016, the Alaska Department of Environmental Conservation (ADEC) submitted an application titled "National Pollutant Discharge Elimination System" for revision/modification to its EPA-approved program under title 40 CFR to allow new electronic reporting. EPA reviewed ADEC's request to revise/modify its EPA-authorized Part 123—EPA Administered Permit Programs: The National Pollutant Discharge Elimination System program and, based on this review, EPA determined that the application met the standards for approval of authorized program revision/modification set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Alaska's request to revise/modify its Part 123—EPA Administered Permit Programs: The National Pollutant Discharge Elimination System program to allow electronic reporting under 40 CFR part 122 is being published in the **Federal Register**.

ADEC was notified of EPA's determination to approve its application with respect to the authorized program listed above.

Matthew Leopard,

Director, Office of Information Collection.

[FR Doc. 2016–22672 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0687; FRL–9951–75–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Stationary Combustion Turbines (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), "NESHAP for Stationary Combustion Turbines (40 CFR part 63, subpart YYYY) (Renewal)" (EPA ICR No. 1967.06, OMB Control No. 2060–0540), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2016. Public comments were previously requested via the **Federal Register** (80 FR 32116) on June 5, 2015, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 21, 2016.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0687, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The affected entities are subject to the General Provisions of the NESHAP (40 CFR part 63, subpart A), and any changes, or additions to the Provisions, which are specified at 40 CFR part 63, subpart YYYY. Owners or operators of the affected facilities must submit an initial notification report, performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports, at a minimum, are required semi-annually.

Form numbers: None.

Respondents/affected entities: Stationary combustion turbines constructed or reconstructed after January 14, 2003.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart YYYY).

Estimated number of respondents: 131 (total).

Frequency of response: Initially, semiannually and annually.

Total estimated burden: 2,220 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $239,000 (per year), which includes $9,700 in either annualized capital/startup or operation & maintenance costs.

Changes in the estimates: There is an adjustment increase in respondent labor hours in this ICR from the most-recently approved ICR. This is due to a projected industry growth, which results in an increase in the estimated number of sources subject to these standards. Additionally, there is a small adjustment decrease in the capital/startup cost due to a correction. The previous ICR incorrectly calculated the labor cost for installing catalyst inlet temperature monitoring devices.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2016–22663 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9952–71–OA]

Notification of a Public Teleconference of the Great Lakes Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) announces a teleconference of the Great Lakes Advisory Board (the Board). The purpose of this teleconference is to discuss the Great Lakes Restoration Initiative covering (GLRI) FY15–19 and other relevant matters.

DATES: The teleconference will be held Tuesday, October 18, 2016 from 10 a.m.

to 12 p.m. Central Time, 11 a.m. to 1 p.m. Eastern Time. An opportunity will be provided to the public to comment.

ADDRESSES: The public teleconference will be held by teleconference only. The teleconference number is: 1–877–226–9607; participant code: 605 016 6037.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this teleconference may contact Taylor Fiscus, Alternate Designated Federal Officer (DFO), by email at *fiscus.taylor@epa.gov.* General information on the Board can be found at *http://glri.us/advisory/index.html.*

SUPPLEMENTARY INFORMATION:

Background: The Board is a federal advisory committee chartered under the Federal Advisory Committee Act (FACA), Public Law 92–463. EPA established the Board in 2013 to provide independent advice to the EPA Administrator in her capacity as Chair of the federal Great Lakes Interagency Task Force (IATF). The Board conducts business in accordance with FACA and related regulations.

The Board consists of 16 members appointed by EPA's Administrator in her capacity as IATF Chair. Members serve as representatives of state, local and tribal government, environmental groups, agriculture, business, transportation and as technical experts.

Availability of Teleconference Materials: The agenda and other materials in support of the teleconference will be available on the Board Web site at *http://glri.us/advisory/index.html.*

Procedures for Providing Public Input: Federal advisory committees provide independent advice to federal agencies. Members of the public can submit relevant comments for consideration by the Board. Input from the public to the Board will have the most impact if it provides specific information for the Board to consider. Members of the public wishing to provide comments should contact the Alternate DFO directly.

Oral Statements: In general, individuals or groups requesting to provide comments or oral presentation at this public teleconference will be limited to three minutes per speaker, subject to the number of people wanting to comment. Interested parties should contact the Alternate DFO in writing (preferably via email) at the contact information noted above by October 11, 2016 to be placed on the list of public speakers for the teleconference.

Written Statements: Written statements must be received by October 11, 2016 so that the information may be made available to the Board for consideration. Written statements should be supplied to the Alternate DFO in the following formats: One hard copy with original signature and one electronic copy via email. Commenters are requested to provide two versions of each document submitted: One each with and without signatures because only documents without signatures may be published on the Board Web page.

Accessibility: For information on access or services for individuals with disabilities, please contact the Alternate DFO at the email address noted above, preferably at least seven days prior to the teleconference to give EPA as much time as possible to process your request.

Dated: September 12, 2016.

Cameron Davis,

Senior Advisor to the Administrator.

[FR Doc. 2016–22771 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2016–0445; FRL–9950–75]

Correction; Summitec Corporation, Versar, Inc., and CDM/CSS-Dynamac Joint Venture; Transfer of Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; correction.

SUMMARY: This is a correction to the notice that published in the **Federal Register** of August 10, 2016, which announced that pesticide related information submitted to EPA's Office of Pesticide Programs (OPP) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), including information that may have been claimed as Confidential Business Information (CBI) by the submitter, will be transferred in accordance with the CBI regulations. That notice incorrectly identified the contractor as "Summitec Corporation and listed its subcontractors as Versar, Inc., and CDM/CSS-Dynamac Joint Venture. In this notice, EPA is correctly listing the main contractors as Summitec Corporation, Versar, Inc. and CDM/CSS-Dynamac Joint Venture; and is also providing their respective subcontractors. This document corrects the listings in the notice of August 10, 2016.

FOR FURTHER INFORMATION CONTACT: Mario Steadman, Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–8338; email address: *steadman.mario@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

This is a correction to the notice that published in the **Federal Register** of August 10, 2016 (81 FR 52852) (FRL–9950–09). In that notice, EPA incorrectly identified a single contract (Contract No. EP–W–16–019) as having been awarded to "Summitec Corporation and its subcontractors, Versar, Inc., and CDM/CSS-Dynamac Joint Venture." Instead, the notice should have identified the work as having been awarded under the following three contracts:

- Contract No. EP–W–16–018: CDM/CSS-Dynamac Joint Venture and its subcontractors (Stone Environmental Inc., WinTech, LLC, Gibb Epidemiology Consulting, LLC, Global VetPathology, Corona Environmental Consulting, LLC, and WorkSafe Resources, LLC);
- Contract No. EP–W–16–019: Summitec Corporation and its subcontractor (SRC); and
- Contract No. EP–W–16–020: Versar, Inc. and its subcontractors (Abt Associates, EnDyna, Exponent, Inc., Essential Software, Inc., BrownGlove Consulting Group and Information Impact).

II. Contract Requirements

The work to be performed by these contractors is described in the notice of August 10, 2016. OPP has determined that providing these companies with access to information on all pesticide chemicals is necessary for the performance of this contract. The information, some of which may be entitled to confidential treatment, has been submitted to EPA under FIFRA sections 3, 4, 6, and 7 and under FFDCA sections 408 and 409. In accordance with the requirements of 40 CFR 2.307(h)(2), the contract with each company prohibits use of the information for any purpose not specified in the contract; prohibits disclosure of the information to a third party without prior written approval from the Agency; and requires that each official and employee of the contractor sign an agreement to protect the information from unauthorized release and to handle it in accordance with the *FIFRA Information Security Manual.* In addition, these companies are required to submit for EPA approval a security plan under which any CBI will be secured and protected against unauthorized release or compromise. No information will be provided to any of these companies until the requirements in this document have been fully satisfied. Records of information provided to these companies will be maintained by EPA project officers for this contract. All information supplied by EPA for use in connection with this contract will be returned to EPA when the companies have completed their work.

Authority: 7 U.S.C. 136 *et seq.;* 21 U.S.C. 301 *et seq.*

Dated: September 8, 2016.

Delores J. Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2016–22762 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0690; FRL–9952–37–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Automobile and Light-Duty Truck Surface Coating (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), "NESHAP for Automobile and Light-duty Truck Surface Coating (40 CFR part 63, subpart IIII) (Renewal)" (EPA ICR No. 2045.06, OMB Control No. 2060–0550), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2016. Public comments were previously-requested via the **Federal Register** (80 FR 32116) on June 5, 2015 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 21, 2016.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0690, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The affected entities are subject to the General Provisions of the NESHAP (40 CFR part 63, subpart A), and any changes, or additions, to the Provisions are specified at 40 CFR part 63, subpart IIII. Owners or operators of the affected facilities must submit initial notification reports, performance tests, and periodic reports, and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports, at a minimum, are required semiannually.

Form numbers: None.

Respondents/affected entities: Facilities that perform surface coating on automobiles and light-duty trucks.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart IIII).

Estimated number of respondents: 65 (total).

Frequency of response: Initially, occasionally and semiannually.

Total estimated burden: 26,700 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $2,830,000 (per year), which includes $78,000 in either annualized capital/startup or operation & maintenance costs.

Changes in the estimates: There is a small adjustment increase in respondent labor hours in this ICR from the most recently approved ICR due to rounding. This ICR rounds the total estimated burden hours and costs to three significant digits.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2016–22664 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0662; FRL–9952–36–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Gasoline Distribution Facilities (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), "NESHAP for Gasoline Distribution Facilities (40 CFR part 63, subpart R) (Renewal)" (EPA ICR No. 1659.09, OMB Control No. 2060–0325), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2016. Public comments were requested previously via the **Federal Register** (80 FR 32116) on June 5, 2015 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 21, 2016.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–

HQ–OECA–2012–0662, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of affected facilities are required to comply with reporting and/or record keeping requirements for the NESHAP General Provisions at 40 CFR part 63, subpart A, as well as for the specific requirements at 40 CFR part 63, subpart R. This includes submitting initial notification reports, performance tests and periodic reports and results, maintaining records of the occurrence and duration of any startup, shutdown or malfunction in the operation of an affected facility or any period during which the monitoring system is inoperative, and maintaining records of annual certification testing if an area source is within 50 percent of major source threshold criteria. These reports are used by EPA to determine compliance with the standards.

Form numbers: None.

Respondents/affected entities: Bulk gasoline terminals.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart R).

Estimated number of respondents: 492 (total).

Frequency of response: Initially and semiannually.

Total estimated burden: 15,900 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $2,000,000 (per year), which includes $357,000 in either annualized capital/startup or operation & maintenance costs.

Changes in the estimates: There is an adjustment increase in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The small change in the burden and cost estimates occurred because of a change in assumption. This ICR assumes all sources will have to familiarize themselves with the regulatory requirements each year.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2016–22670 Filed 9–20–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

[Notice 2016–09]

Filing Dates for the Kentucky Special Election in the 1st Congressional District

AGENCY: Federal Election Commission.

ACTION: Notice of filing dates for special election.

SUMMARY: Kentucky has scheduled a special general election on November 8, 2016, to fill the U.S. House of Representatives seat in the 1st Congressional District vacated by Representative Ed Whitfield.

Committees required to file reports in connection with the Special General Election on November 8, 2016, shall file a 12-day Pre-General Report, and a 30-day Post-General Report.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth S. Kurland, Information Division, 999 E Street NW., Washington, DC 20463; Telephone: (202) 694–1100; Toll Free (800) 424–9530.

SUPPLEMENTARY INFORMATION:

Principal Campaign Committees

All principal campaign committees of candidates who participate in the Kentucky Special General Election shall file a 12-day Pre-General Report on October 27, 2016; and a Post-General Report on December 8, 2016. (See chart below for the closing date for each report.)

Note that these reports are in addition to the campaign committee's regular quarterly filings. (See chart below for the closing date for each report).

Unauthorized Committees (PACs and Party Committees)

Political committees filing on a quarterly basis in 2016 are subject to special election reporting if they make previously undisclosed contributions or expenditures in connection with the Kentucky Special General Election by the close of books for the applicable report(s). (See chart below for the closing date for each report.)

Committees filing monthly that make contributions or expenditures in connection with the Kentucky Special General Election will continue to file according to the monthly reporting schedule.

Additional disclosure information in connection with the Kentucky Special General Election may be found on the FEC Web site at *http://www.fec.gov/info/report_dates.shtml.*

Disclosure of Lobbyist Bundling Activity

Principal campaign committees, party committees and Leadership PACs that are otherwise required to file reports in connection with the special general election must simultaneously file FEC Form 3L if they receive two or more bundled contributions from lobbyists/registrants or lobbyist/registrant PACs that aggregate in excess of the $17,600 during the special election reporting periods. (See chart below for closing date of each period.) 11 CFR 104.22(a)(5)(v), (b).

CALENDAR OF REPORTING DATES FOR KENTUCKY SPECIAL GENERAL ELECTION

Report	Close of books[1]	Reg./cert. and overnight mailing deadline	Filing deadline
Committees Involved in the Special General (11/08/16) Must File			
Pre-General	10/19/16	10/24/16	10/27/16
Post-General	11/28/16	12/08/16	12/08/16
Year-End	12/31/16	01/31/17	01/31/17

[1] The reporting period always begins the day after the closing date of the last report filed. If the committee is new and has not previously filed a report, the first report must cover all activity that occurred before the committee registered as a political committee up through the close of books for the first report due.

On behalf of the Commission.

Dated: September 12, 2016.

Matthew S. Petersen,

Chairman, Federal Election Commission.

[FR Doc. 2016–22685 Filed 9–20–16; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 002206–008.

Title: California Association of Port Authorities—Northwest Marine Terminal Association Terminal Discussion Agreement.

Parties: California Association of Port Authorities; and Northwest Marine Terminal Association.

Filing Party: Jaime Amador, Executive Officer; Northwest Marine Terminal Association; P.O. Box 1970, Shelton, WA 98584.

Synopsis: The amendment would add the Northwest Seaport Alliance as a member to the Northwest Marine Terminal Association and reflect the withdrawal of the Port of Tacoma from the Northwest Marine Terminal Association.

Agreement No.: 009335–009.

Title: Northwest Marine Terminal Association, Inc. Agreement.

Parties: Port of Anacortes; Port of Astoria; Port of Bellingham; Port of Coos Bay; Port of Everett; Port of Grays Harbor; Port of Kalama; Port of Longview; Port of Olympia; Port of Pasco; Port of Port Angeles; Port of Portland; Port of Seattle; Port of St. Helens; Port of Tacoma; and Port of Vancouver, USA.

Filing Party: Jaime Amador, Executive Officer; Northwest Marine Terminal Association; P.O. Box 1970, Shelton, WA 98584.

Synopsis: The amendment would add the Northwest Seaport Alliance as a member to the agreement.

By Order of the Federal Maritime Commission.

Dated: September 16, 2016.

Karen V. Gregory,

Managing Director.

[FR Doc. 2016–22773 Filed 9–20–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 2016–20201) published on page 57909 of the issue for Wednesday, August 24, 2016.

Under the Federal Reserve Bank of San Francisco, heading, the entry for *The Living Trust for the Benefit of Stephanie M. Smith, Helen Langer Smith, and Cynthia L. Smith; Kitsap, Washington,* is revised to read as follows:

A. Federal Reserve Bank of San Francisco (Gerald C. Tsai, Director, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *The Living Trust for the Benefit of Stephanie M. Smith, Brian S. Sato, Cynthia L. Smith, all from Mercer Island, Washington; Helen Langer Smith and Meredith P. Smith, both of Port Orchard, Washington,* as Trustees for the Living Trust for the Benefit of Stephanie M. Smith; and Michael K. Pigors, Memphis, Tennessee, to retain additional shares of Olympic Bancorp, Inc., and thereby indirectly retain voting shares of Kitsap Bank, both of Port Orchard, Washington.

Comments on this application must be received by October 7, 2016.

Board of Governors of the Federal Reserve System, September 16, 2016.

Margaret M. Shanks,

Deputy Secretary of the Board.

[FR Doc. 2016–22734 Filed 9–20–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of

Governors not later than October 17, 2016.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *First State Bancshares, Inc., New London, Wisconsin;* to merge with Rudolph Bancshares, Inc., and thereby indirectly control Farmers and Merchants Bank, both of Rudolph, Wisconsin.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) One Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Goering Management Company, LLC, and Goering Financial Holding Company Partnership, LP, both of Moundridge, Kansas;* to acquire additional shares, for a total ownership up to 65 percent of the voting shares, of Bon, Inc., parent of The Citizens State Bank, both in Moundridge, Kansas.

C. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. *Regal Bancorp Inc., Livingston, New Jersey;* to become a bank holding company by acquiring 100 percent of the outstanding stock of Regal Bank, Livingston, New Jersey.

Board of Governors of the Federal Reserve System, September 16, 2016.

Margaret M. Shanks,

Deputy Secretary of the Board.

[FR Doc. 2016–22733 Filed 9–20–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than October 5, 2016.

A. *Federal Reserve Bank of Kansas City* (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Kara L. Marshall Kelley, Omaha, Nebraska; as trustee of various trusts, and Kristen L. Marshall Maser, Grand Island, Nebraska, as trustee of various trusts, William W. Marshall III 2006 Irrevocable Life Insurance Trust; the 2016 Sharon Marshall Irrevocable HBC Trust; and HBC Investments, LLC; all of Grand Island, Nebraska; and for approval as a member of the Marshall Family Group: Sharon L. Marshall, Matthew Maser, the William W. Marshall III Revocable Trust, the Sharon L. Marshall Irrevocable Dynasty Trust, the Kristen L. Marshall Maser Revocable Trust, the Katherine Marshall Maser Irrevocable Trust, the Carolyn Marshall Maser Irrevocable Trust, the William Marshall Maser Irrevocable Trust, all of Grand Island, Nebraska; and Thomas O. Kelley, the Kara L. Marshall-Kelley Revocable Trust, the Kathleen Grace Kelley Irrevocable Trust, the Thomas O. Kelley Irrevocable Trust, the John Marshall Kelley Irrevocable Trust, all of Omaha, Nebraska;* to acquire shares of and Hometown Banc Corp, Grand Island, Nebraska, and thereby control Five Points Bank, Grand Island, Nebraska, and Five Points Bank of Hastings, Hastings, Nebraska.

B. *Federal Reserve Bank of Dallas* (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Mickey Wiley Carter, Sr., as co-trustee of Carter Holdings Trust, both of Omaha, Texas;* to join the Holton Family Group and to retain control of the voting shares of WSB Bancshares, Inc., Wellington, Texas, and indirectly retain shares of Wellington State Bank, Wellington, Texas.

Board of Governors of the Federal Reserve System, September 15, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–22636 Filed 9–20–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 14, 2016.

A. *Federal Reserve Bank of Philadelphia* (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org*:

1. *HV Bancorp, Inc., Huntingdon, Pennsylvania;* to become a bank holding company by acquiring 100 percent of Huntingdon Valley Bank, Huntingdon, Pennsylvania, upon its conversion to a stock savings bank.

Board of Governors of the Federal Reserve System, September 15, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–22637 Filed 9–20–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Unaccompanied Refugee Minors Placement and Outcomes Reports; ORR–3 and ORR–4.

OMB No.: 0970–0034.

Description: As required by section 412(d) of the Immigration and Nationality Act, the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is requesting the information from report

Form ORR–3 and ORR–4 to administer the Unaccompanied Refugee Minors (URM) program. The ORR–3 (Placement Report) is submitted to ORR by the State agency at the minor's initial placement in the resettlement State within 30 days of the placement, and whenever there is a change in the minor's status, including termination from the program, within 60 days of the change or closure of the case. The ORR–4 (Outcomes Report) is submitted every 12 months beginning on the 12 month anniversary date of initial placement to record outcomes of the child's progress toward the goals listed in the child's case plan. An ORR–4 is also submitted along with the initial ORR–3 report for minors 17 years old or above to establish a baseline of information for the youth related to independent living and/or educational plans. The ORR regulations per 45 CFR 400.120 describe specific URM program reporting requirements.

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–3	15	Estimated responses 178	0.25 (15 min)	Estimated 667.5.
ORR–4	15	Estimated responses 127	1.5 (1 hour and 30 min)	Estimated 2,857.5.
Estimated Total Annual Burden Hours.				3,525.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–22678 Filed 9–20–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2730]

Food and Drug Administration's Application of Statutory Factors in Determining When a Risk Evaluation and Mitigation Strategy Is Necessary; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "FDA's Application of Statutory Factors in Determining When a REMS Is Necessary." This draft guidance is intended to clarify how FDA applies the factors set forth in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) in determining whether a risk evaluation and mitigation strategy (REMS) is necessary to ensure that the benefits of a drug outweigh its risks. This guidance is one of several being developed to fulfill performance goals that FDA agreed to satisfy in the context of the fifth reauthorization of the prescription drug user fee program (the Prescription Drug User Fee Act V).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 21, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments,

except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–2730 for the "FDA's Application of Statutory Factors in Determining When a REMS Is Necessary; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Aaron Sherman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993, 240–402–0493, *Aaron.Sherman@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "FDA's Application of Statutory Factors in Determining When a REMS Is Necessary." The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) created section 505–1 of the FD&C Act (21 U.S.C. 355–1),[1] which authorizes FDA to require a REMS for certain drugs if FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks (see section 505–1(a) of the FD&C Act). A REMS is a required risk management strategy that can include one or more elements to ensure that the benefits of a drug outweigh its risks (see section 505–1(e) of the FD&C Act). A REMS may consist of a Medication Guide, a patient package insert, and/or a communication plan (section 505–1(e)(2) to (e)(3) of the FD&C Act). FDA may also require certain elements to assure safe use (ETASU) as part of a REMS for a drug (see section 505–1(f) of the FD&C Act). (The ETASU can include, for example, requirements that health care providers who prescribe the drug have particular training or experience, that patients using the drug be monitored, or that the drug be dispensed to patients with evidence or other documentation of safe use conditions (Id.). The ETASU may also include an implementation system through which the sponsor is able to monitor, evaluate, and improve implementation of the ETASU (see section 505–1(f)(4) of the FD&C Act).) Finally, REMS generally must have a timetable for submission of assessments of the strategy (see section 505–1(d) of the FD&C Act). FDA can require a REMS before initial approval of a new drug application or, should FDA become aware of "new safety information" (as defined in section 505–1(b)(3) of the FD&C Act) about a drug and determine that a REMS is necessary to ensure that the benefits of the drug outweigh its risks, after the drug has been approved (see section 505–1(a)(2) of the FD&C Act).

FDA's determination as to whether a REMS is necessary for a particular drug is a complex, drug-specific inquiry, reflecting an analysis of multiple, interrelated factors. In conducting this analysis, FDA considers whether (based on premarketing or postmarketing risk assessments) there is a particular risk associated with the use of the drug that, on balance, outweighs its benefits and whether additional interventions beyond FDA-approved labeling are necessary to ensure that the drug's benefits outweigh its risks.

If FDA determines that additional interventions are necessary to ensure that the benefits of a drug outweigh its risks, FDA considers what the goals of a proposed REMS to address these risks would be and what specific elements could help meet those goals. If a REMS can be designed that FDA expects will meet the relevant goals and not unduly impede patient access to the drug, then FDA will generally approve the drug with a REMS (or, if the drug is already being marketed, require that a REMS be imposed for the drug). If FDA believes that the drug's risks would exceed its benefits even if FDA were to require a REMS for the drug, FDA will not approve the drug or may consider seeking withdrawal of the drug if it is already being marketed.

FDAAA requires FDA to consider the following six factors [2] in making a decision about whether to require a REMS:

---

[1] Section 505–1 of the FD&C Act applies to applications for prescription drugs submitted or approved under subsections 505(b) (*i.e.*, new drug applications) or (j) (*i.e.*, abbreviated new drug applications) of the FD&C Act and to applications submitted or approved under section 351 (*i.e.*, biologics license applications) of the Public Health Service Act (42 U.S.C. 262). In this document, unless otherwise specified, the term "drug" refers to drug and biological products (or biologics).

[2] Section 505–1(a)(1) of the FD&C Act requires the Agency to consider these factors in determining whether a REMS is necessary for a new drug. FDA also generally considers these factors in determining whether (based on new safety information), a REMS is necessary for a drug that is the subject of an approved application.

- The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug
- The expected benefit of the drug with respect to the disease or condition
- The seriousness of the disease or condition that is to be treated with the drug
- Whether the drug is a new molecular entity
- The expected or actual duration of treatment with the drug
- The estimated size of the population likely to use the drug

These six factors influence FDA's decisions with respect to both whether a REMS is required for a particular drug and what type of REMS might be necessary (*i.e.*, what specific elements/tools should be included as part of the REMS). FDA makes decisions about requiring a REMS as part of a benefit-risk determination for a drug after an evaluation that includes integrated consideration of each of the statutory factors. No single factor, by itself, is determinative as to whether a REMS is necessary to ensure that the benefits of a drug outweigh its risks. This guidance describes how FDA considers each of these factors in conducting its REMS analysis.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on how the Agency applies statutory factors in determining when a REMS is necessary. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: September 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22689 Filed 9–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2561]

Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled "Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices." This draft guidance is intended to assist drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs and antimicrobial susceptibility test (AST) devices and who seek to coordinate development of these products such that the AST device could be cleared either at the time of new drug approval or shortly thereafter. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 21, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–2561 for "Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Alternatively, you may submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to the office that you are ordering from to assist in processing your request.

FOR FURTHER INFORMATION CONTACT: Ribhi Shawar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4604, Silver Spring, MD 20993–0002, 301–796–6698; or Joseph Toerner, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance, when finalized, is intended to assist drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs and AST devices and who seek to coordinate development of these products such that the AST device could be cleared either at the time of new drug approval or shortly thereafter.

Specifically, the guidance intends to describe the interactions between drug sponsors and device manufacturers for coordinated development of a new antimicrobial drug and an AST device; explain the considerations for submitting separate applications to the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) when seeking clearance of an AST device coincident with, or soon following, antimicrobial drug approval; and clarify that the review of the new antimicrobial drug product and AST device(s) will remain independent, and that coordinated development does not influence the review timelines for either product.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on coordinated development of antimicrobial drugs and antimicrobial susceptibility test devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* and a search capability for all Center for Drug Evaluation and Research guidance documents is available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of "Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices" may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400061 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120, the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078, the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in the guidance document "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" have been approved under OMB control number 0910–0756.

Dated: September 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22711 Filed 9–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0081]

Armenpharm, Ltd.; Suspension of Approval of an Abbreviated New Drug Application for Chloramphenicol Capsules, 250 Milligrams; Determination That CHLOROMYCETIN (Chloramphenicol) Capsules, 50 Milligrams and 100 Milligrams, and Three Other Products Were Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is suspending approval of abbreviated new drug application (ANDA) 060851 for chloramphenicol capsules, 250 milligrams (mg), held by Armenpharm, Ltd. (Armenpharm), 49 South Ridge Rd., P.O. Box D1400, Pomona, NY 10970. FDA has also determined that CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg; AMPHICOL (chloramphenicol) Capsules, 100 mg; and CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, 150 mg/5 milliliters (mL), were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve ANDAs for

chloramphenicol capsules, 50 mg and 100 mg, or chloramphenicol palmitate oral suspension, 150 mg/5 mL.

DATES: Effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show, among other requirements, that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. FDA may not approve an ANDA that does not refer to a listed drug.

Section 505(j)(6) of the FD&C Act authorizes FDA to suspend approval of an ANDA if the listed drug relied upon has been withdrawn from sale for what FDA determines are safety or effectiveness reasons. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings under § 314.153(b) (21 CFR 314.153(b)) that could result in the suspension of approval of the ANDAs that refer to the listed drug.

II. Chloramphenicol Capsules, 250 mg

On February 7, 2011, Armenpharm submitted a citizen petition under § 10.30 (Docket No. FDA–2011–P–0081), requesting that the Agency determine whether CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg (ANDA 060591), was withdrawn from sale for reasons of safety or effectiveness. CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, is the listed drug that was the basis of submission for Armenpharm's ANDA 060851 for chloramphenicol capsules, 250 mg. In the **Federal Register** of July 13, 2012 (77 FR 41412), FDA published a notice stating its determination under § 314.161 that CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, was withdrawn from sale for reasons of safety or effectiveness. FDA also notified Armenpharm of the Agency's decision in a letter dated July 13, 2012.

Pursuant to § 314.153(b)(1), FDA initiated the process to suspend Armenpharm's chloramphenicol ANDA 060851 by sending a letter, dated December 3, 2015, notifying Armenpharm of the Agency's initial determination that CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, was withdrawn for reasons of safety or effectiveness and its initial decision to suspend approval of ANDA 060851 (see Docket No. FDA–2011–P–0081). Under § 314.153(b)(2), Armenpharm had 30 days from that notification in which to present written comments or information bearing on the initial decision. On December 17, 2015, Armenpharm submitted comments requesting an oral hearing under § 314.153(b)(4). However, on March 17, 2016, Armenpharm withdrew its oral hearing request.

Therefore, under section 505(j)(6) of the FD&C Act and § 314.153(b), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of ANDA 060851, and all amendments and supplements thereto, is suspended (see DATES). FDA has removed all chloramphenicol capsules, 250 mg, from the list of drug products published in the Orange Book, and no chloramphenicol capsules, 250 mg, will be listed in the Orange Book. Distribution of chloramphenicol capsules, 250 mg, in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

III. Other Discontinued Oral Chloramphenicol Drug Products

FDA has become aware that the oral chloramphenicol drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
ANDA 060591	CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg.	Parkedale Pharmaceuticals Inc. (formerly Parke Davis Pharmaceutical Research Division of Warner Lambert Co.).
ANDA 062301	CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, Equivalent to (EQ) 150 mg base/5 mL.	Parkedale Pharmaceuticals Inc. (formerly Parke Davis Pharmaceutical Research Division of Warner Lambert Co.).
ANDA 060058	AMPHICOL (chloramphenicol) Capsules, 100 mg ...	John J. Ferrante.
NDA 050152	CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, EQ 150 mg base/5mL.	Parkedale Pharmaceuticals Inc. (formerly Parke Davis Pharmaceutical Research Division of Warner Lambert Co.).

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this table were withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed Agency records concerning the withdrawal from sale of the drug products listed in the table. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. At the time of the approval of the drug products listed in the table, there was significant unmet medical need. With the approval of additional therapies with less severe adverse drug effects, FDA has determined that the risks associated with CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg; AMPHICOL (chloramphenicol) Capsules, 100 mg; and CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, 150 mg/5 mL, as currently labeled, outweigh the benefits. Most important, CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg; AMPHICOL (chloramphenicol) Capsules, 100 mg; and CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, 150 mg/5 mL, may cause a number of adverse reactions, the most serious being bone marrow depression (anemia, thrombocytopenia, and granulocytopenia temporally associated with treatment). A boxed warning in the prescribing information for chloramphenicol sodium succinate injection and chloramphenicol capsules and oral suspension states that serious hypoplastic anemia, thrombocytopenia, and granulocytopenia are known to occur after administration of chloramphenicol. The drug product labeling recommends extensive safety monitoring, including baseline blood studies followed by periodic blood studies approximately every 2 days during therapy. The boxed warning also describes fatal aplastic anemia associated with administration of the drug and aplastic anemia attributed to chloramphenicol that later terminated in leukemia. Published literature suggests that the risk of fatal aplastic anemia associated with oral formulations of chloramphenicol may be higher than the risk associated with the intravenous formulation.

FDA has also reviewed approved labeling for the products and has determined that a Risk Evaluation and Mitigation Strategy (REMS) would be required to ensure that the benefits of the drug outweigh its risks. The REMS may include Elements to Assure Safe Use, including restricted distribution, and a Medication Guide could be required as part of the labeling. FDA has determined that additional nonclinical and possibly clinical studies of safety and efficacy would be necessary before CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg; AMPHICOL (chloramphenicol) Capsules, 100 mg; and CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, 150 mg/5 mL, could be considered for reintroduction to the market.

Accordingly, the Agency will remove CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg and 100 mg; AMPHICOL (chloramphenicol) Capsules, 100 mg; and CHLOROMYCETIN PALMITATE (chloramphenicol palmitate) Oral Suspension, 150 mg/5 mL, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to these drug products.

Dated: September 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22660 Filed 9–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1530]

Reporting of Computational Modeling Studies in Medical Device Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Reporting of Computational Modeling Studies in Medical Device Submissions." The purpose of this guidance document is to provide recommendations to industry on the formatting, organization, and content of reports of computational modeling and simulation (CM&S) studies that are used as valid scientific evidence to support medical device submissions, and to assist FDA staff in the review of computational modeling and simulation studies by improving the consistency and predictability of the review of CM&S and facilitating full interpretation and complete review of those studies.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. [FDA–2013–D–1530] for "Reporting of Computational Modeling Studies in Medical Device Submissions." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Reporting of Computational Modeling Studies in Medical Device Submissions" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Tina Morrison, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2204, Silver Spring, MD 20993–0002, 301–796–6310.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled "Reporting of Computational Modeling Studies in Medical Device Submissions." This guidance is intended to provide recommendations to industry on the formatting, organization, and content of reports for CM&S studies that are used as valid scientific evidence to support medical device submissions.

In the **Federal Register** on January 17, 2014 (79 FR 3211), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by April 17, 2014.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Reporting of Computational Modeling Studies in Medical Device Submissions". It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of "Reporting of Computational Modeling Studies in Medical Device Submissions" may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1807 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through E have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332.

Dated: September 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22708 Filed 9–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 045

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 045" (Recognition List Number: 045), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit electronic or written comments concerning this document at any time. These modifications to the list of recognized standards are effective September 21, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2004–N–0451 for "Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 045." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 045.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of Recognition List Number: 045 is available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 045 modifications and other standards related information. Submit written requests for a single hard copy of the document entitled "Modifications to the List of Recognized Standards, Recognition List Number: 045" to Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993, 301–796–6287, *standards@cdrh.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a document published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled "Recognition and Use of Consensus Standards." The document described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

These documents describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 045

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in premarket submissions and other requirements for devices. FDA will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA will use the term "Recognition List Number: 045" to identify these current modifications.

In table 1, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III, FDA lists modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
A. General I (Quality Systems/Risk Management) (QS/RM)			
5–85		IEC 60601–1–6 Edition 3.0 2010–01 Medical electrical equipment—Part 1–6: General requirements for basic safety and essential performance—Collateral standard: Usability.	Withdrawn. See Rec# 5–89.
5–86		IEC 60601–1–8 Edition 2.0 2006–10 Medical electrical equipment—Part 1–8: General requirements for basic safety and essential performance—Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.	Withdrawn. See Rec# 5–76.
5–106	5–109	ISO 80369–3 First edition 2016–07–01 Small-bore connectors for liquids and gases in healthcare applications—Part 3: Connectors for enteral applications.	Withdrawn and replaced with newer version.
B. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19–3		IEC 60601–1–10 Edition 1.0 2007–11 Medical electrical equipment—Part 1–10: General requirements for basic safety and essential performance—Collateral standard: Requirements for the development of physiologic closed-loop controllers.	Withdrawn. See Rec# 19–9.
19–5		AAMI/ANSI ES60601–1:2005/(R) 2012 and C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated text) Medical electrical equipment—Part 1: General requirements for basic safety and essential performance (IEC 60601–1:2005, MOD).	Withdrawn. See Rec# 19–4.
C. General Hospital/General Plastic Surgery (GH/GPS)			
6–362	6–379	ISO 7864 Fourth edition 2016–08–01 Sterile hypodermic needles for single use—Requirements and test methods.	Withdrawn and replaced with newer version.
6–366	6–380	ISO 9626 Second edition 2016–08–01 Stainless steel needle tubing for the manufacture of medical devices—Requirements and test methods.	Withdrawn and replaced with newer version.
6–376	6–381	ISO 6009 Fourth edition 2016–08–01 Hypodermic needles for single use—Colour coding for identification.	Withdrawn and replaced with a newer version.
6–378	6–382	ISO 11608–7 First edition 2016–08–01 Needle-based injection systems for medical use—Requirements and test methods—Part 7: Accessibility for persons with visual impairment.	Withdrawn and replaced with a newer version.
D. Obstetrics-Gynecology (OB–GYN)/Gastroenterology/Urology			
9–61		IEC 60601–2–18 Edition 3.0 2009–08 Medical electrical equipment—Part 2–18: Particular requirements for the basic safety and essential performance of endoscopic equipment.	Combined with 4–187.
E. Ophthalmic			
10–51		ISO 15004–2 First edition 2007–02–15 Ophthalmic Instruments—Fundamental requirements and test methods—Part 2: Light hazard protection.	Transition period.
F. Radiology			
12–208		IEC 60601–2–22 Third Edition 2007–05 Medical electrical equipment—Part 2–22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.	Withdrawn. See Rec# 12–268.
12–210		IEC 60601–1–3 Edition 2.0 2008–01 Medical electrical equipment—Part 1–3: General requirements for basic safety and essential performance—Collateral standard: Radiation protection in diagnostic x-ray equipment.	Withdrawn. See Rec# 12–269.

[1] All standard titles in this table conform to the style requirements of the respective organizations

III. Listing of New Entries

In table 2, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 045.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard[1]	Reference No. and date
A. General I (Quality Systems/Risk Management) (QS/RM)		
5–110	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.	ISTA 3A 2008.
5–111	Packaged-Products for Less-Than-Truckload (LTL) Shipment	ISTA 3B 2012.
5–112	Unitized Loads of Same Product	ISTA 3E 2009.
B. In Vitro Diagnostics (IVD)		
7–265	Liquid Chromatography-Mass Spectrometry Methods; Approved Guideline.	C62–A: 2014.
7–266	A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures.	EP19 Second Edition: 2015.
C. Ophthalmic		
10–101	Ophthalmic optics—Contact lenses and contact lens care products—Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interactions.	ISO 18189 First edition 2016–06–01.
10–102	American National Standard for Ophthalmics—Light Hazard Protection for Ophthalmic Instruments.	ANSI Z80.36—2016.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA Recognized Consensus Standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* FDA will incorporate the modifications and revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary. Beginning with Recognition List 033, FDA no longer announces minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, processes affected, Code of Federal Regulations citations, and product codes.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to *standards@cdrh.fda.gov.* To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page, *http://www.fda.gov/MedicalDevices,* includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the **Federal Register**, this notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 045" will be available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

Dated: September 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22710 Filed 9–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Prokaryotic Gene Expression.

Date: October 5, 2016.

Time: 9:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard A. Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Rehabilitation Sciences Study Section.

Date: October 17, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin BWI, 1110 Old Elkridge Landing Road, Linthicum, MD 21090.

Contact Person: Maria Nurminskaya, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 435–1222, *nurminskayam@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Virology—B Study Section.

Date: October 17–18, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Alexandria Old Town, 1456 Duke St, Alexandria, VA 22314.

Contact Person: John C. Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435–2398, *pughjohn@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Mechanisms of Sensory, Perceptual, and Cognitive Processes Study Section.

Date: October 17–18, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005.

Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, *kgt@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Vaccine Related Immune Activation and Immunoregulation.

Date: October 18, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Liying Guo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016F, Bethesda, MD 20892, 301–435–0908, *lguo@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–16–114: Spermatogenic Stem Cell Culture Systems to Preserve and Restore Reproductive Capacity in Males.

Date: October 19, 2016.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Clara M. Cheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301–435–1041, *chengc@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 15, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22666 Filed 9–20–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NHLBI. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NHLBI.

Date: October 25, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Robert S. Balaban, Ph.D., Scientific Director, National Heart, Lung, and Blood Institute, National Institutes of Health, Building 10, 10 Center Drive, CRC, 4th Floor, Room 1581, Bethesda, MD 20892, 301–496–2116, *balabanr@nhlbi.nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 15, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22667 Filed 9–20–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Microenvironment Study Section.

Date: October 13–14, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Angela Y. Ng, MBA, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, Bethesda, MD 20892, 301–435–1715, *ngan@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cellular Aspects of Diabetes and Obesity.

Date: October 13, 2016.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, EMNR IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182 MSC 7892, Bethesda, MD 20892, 301 435–2514, *riverase@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–AI–16–024: Sustained-Release Anti-HIV Products.

Date: October 14, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry B Study Section.

Date: October 19–20, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Eissenstat, Ph.D., Scientific Review Officer, BCMB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301–435–1722, *eissenstatma@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroendocrinology, Neuroimmunology, Rhythms and Sleep Study Section.

Date: October 19–20, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *mselmanoff@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function D Study Section.

Date: October 19, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

Contact Person: James W. Mack, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4154, MSC 7806, Bethesda, MD 20892, (301) 435–2037, *mackj2@csr.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Cancer Molecular Pathobiology Study Section.

Date: October 19–20, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Manzoor Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Musculoskeletal, Oral and Skin Sciences AREA Review.

Date: October 19, 2016.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Aftab A. Ansari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, 301–237–9931, *ansaria@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; BD2K Open Educational Resources for Data Science (R25).

Date: October 19, 2016.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Craig Giroux, Ph.D., Scientific Review Officer, BST IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, Bethesda, MD 20892, 301–435–2204, *girouxcn@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; SBIB Clinical Pediatric and Fetal Applications.

Date: October 19, 2016.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Songtao Liu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Rm 5108, Bethesda, MD 20817, 301–435–3578, *songtao.liu@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 15, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22665 Filed 9–20–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is issuing this policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through *ClinicalTrials.gov.* The policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at *ClinicalTrials.gov,* and that results information of these trials is submitted to *ClinicalTrials.gov.*

DATES: This policy will take effect January 18, 2017.

FOR FURTHER INFORMATION CONTACT: For information about the policy, please contact the NIH Office of Science Policy at *clinicaltrials.disseminationpolicy@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The policy is complementary to the statutory and regulatory reporting requirements. These are section 402(j) of the Public Health Service Act, as amended by Title VIII of the Food and Drug Administration (FDA) Amendments Act of 2007 (FDAAA), and the regulation Clinical Trial Registration and Results Information Submission, at 42 CFR part 11. Hereafter, we refer to section 402(j) as the statute and 42 CFR part 11 as the rule or regulation.

On November 19, 2014, and in tandem with the publication of the Notice of Proposed Rulemaking (NPRM) on Clinical Trial Registration and Results Submission, the NIH issued a complementary draft policy for public comment on the Dissemination of NIH-funded Clinical Trial Information [Ref. 1, 2]. The draft policy proposed that all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by the NIH, regardless of study phase, type of intervention, or whether they are subject to the statutory registration and results information submission requirements, would be expected to ensure that those clinical trials are registered and results information is submitted to *ClinicalTrials.gov*. It further stated that submission of the same type of registration and results information would be expected and in the same timeframes as the trials subject to the statute, and that this information would be made publicly available through the *ClinicalTrials.gov* Web site.

The NIH received approximately 240 public comments on its proposed policy. The comments came from a range of stakeholders including researchers, academic/research institutions, medical practitioners, patients, patient/disease advocacy groups, scientific/professional societies and associations, device manufacturers, trade associations, not-for-profit non-governmental organizations, and the general public [Ref. 3]. The NIH appreciated the public interest in the proposed policy and the time made and effort taken by stakeholders to provide comments. The NIH carefully considered those comments in the development of the final policy. In the next section, we provide an overview of the comments on the proposed policy. Because those in compliance with the policy would be expected to follow specific provisions of the rule, a number of commenters on the policy reiterated comments that they submitted to the docket in response to the NPRM [Ref. 4]. Since these comments are discussed at length in the preamble of the rule, we are limiting the discussion of comments here primarily to those that identified issues specific to the policy, such as its scope, applicability, and impact on NIH-funded awardees and investigators.

Overview of the Public Comments

A significant majority of the public comments were supportive of the proposed NIH policy and of its application to the full range of NIH-funded clinical trials. Most commenters appreciated the impetus behind the policy and agreed that it was important to provide ways other than journal publication for clinical trial results to be disseminated and made publicly available to researchers, health care providers, and patient communities. They recognized that increased availability of information from NIH-funded clinical trials would help researchers by informing the design and development of their future studies, address the needs of patients and healthcare providers seeking information about NIH-funded trials, and serve the public's interest by preventing duplication of unsafe and unsuccessful trials and mitigating publication bias. They also agreed that improving the availability of clinical trial information will strengthen the public's trust in biomedical research as well as assure volunteers that their participation in clinical trials has advanced knowledge on human health and disease. A number of commenters also suggested that the policy is particularly appropriate because NIH-funded clinical trials are supported by public funding, and recipients of those funds have a special obligation to ensure that the nation's investment is maximized.

A number of comments from academic investigators and stakeholder organizations were supportive of the policy and its goals. Others, however, disagreed with the policy, suggesting that it was ill-advised and/or unnecessary. These commenters suggested that the benefit of greater transparency was outweighed by the burden and cost of the policy to those who conduct clinical trials and that the NIH had not made a sufficient case for the policy or that it was not evidence-based. Some commenters suggested that the NIH should simply encourage investigators to be more transparent or that the NIH's public access policy made the policy unnecessary since it requires NIH-funded investigators to make their published articles publicly available through PubMed Central.

Scope and Applicability of the Policy. Although the majority of commenters fully supported the scope of the policy, *i.e.*, that it should apply to NIH-funded clinical trials of FDA-regulated drugs regardless of phase, small feasibility studies of devices, and trials of interventions not regulated by FDA, including surgical and behavioral interventions, there were comments suggesting that the scope was too narrow, or conversely, too broad.

One commenter suggested that the policy ought to encompass more detailed summary results, such as Clinical Study Reports, as well as de-identified individual patient-level data. One commenter suggested that the NIH should consider extending the policy to preclinical *in vivo* (laboratory) animal studies because the arguments for the registration and required reporting of preclinical *in vivo* (laboratory) animal studies are similar to those of human clinical trials. Some commenters suggested that the policy should be retroactive and apply to clinical trials that are underway as of the policy's effective date as well as those that have already been completed as of the effective date.

On the other hand, there were other comments suggesting that the policy should not apply to phase 1 or so called phase 0 trials, pilot trials designed to examine the feasibility of an approach, trials mounted by an investigator at a small organization, or trials that are unable to enroll a statistically significant number of participants. One suggested that even pilot trials that reach their enrollment target should not be expected to submit results information because the results might be more misleading than helpful. Another proposed that reporting on phase 1 clinical trials should be limited to adverse events information because these trials are designed to assess safety rather than efficacy, and reporting non-safety outcomes could be misleading. Another suggested that clinical trials not covered under the statute should not submit adverse event information unless a regulatory authority or equivalent body has first performed an analysis of the event in order to prevent public misunderstanding. Another commenter suggested that submission of data from early phase research could divert limited research resources and time from phase 3 studies. Another suggested that only information about phase 3 clinical trials should be included in *ClinicalTrials.gov* because information about early stage trials could confound, rather than enhance, public understanding of human health and could, thereby, inadvertently adversely affect patient safety.

One commenter suggested that the policy should apply only to the registration of clinical trials, not the submission of results information. This commenter asserted that registration information was sufficient because any interested party could follow up with an investigator to learn more about the trial and because submission of registration information takes a fraction of the time needed to submit results information.

There were a few commenters who took issue with the application of the policy to trials that are only partially funded by the NIH. They asserted that the policy would entail the disclosure of confidential commercial information and that the NIH's authority to do so is limited to a trial that is wholly NIH-funded and involves a product with research and development costs wholly government-funded. A few other commenters suggested that the policy should exclude clinical trials that use NIH-supported infrastructure, but involve no NIH funds.

NIH Definition of Clinical Trial. Some commenters addressed the NIH definition of clinical trial, which is key to determining the policy's applicability. There was support for the breadth of the definition, *i.e.,* encompassing all interventional studies with biomedical outcomes (*e.g.,* pharmacokinetic and behavioral outcomes, as well as health-related outcomes). One commenter, however, thought more elaboration on the definition was needed to clarify the meaning of "health-related biomedical or behavioral outcomes." They thought that without such specificity, the definition might be interpreted to exclude studies that contain valuable information for public health research, science, and clinical medicine. Commenters believed that addressing this issue would be vital to ensure a common understanding that the NIH policy applies to all clinical trials involving a biomedical or behavioral intervention. Another suggested that a study involving only one participant should not be considered a clinical trial since a trial with a sample size of one would not provide any valid data to share with the public.

Some commenters noted that the wording of the NIH definition was not identical to the wording of the definition of clinical trial in the proposed rule or to how other organizations, *e.g.,* the World Health Organization (WHO), International Committee of Medical Journal Editors (ICMJE), and Centers for Medicare & Medicaid Services (CMS), use the term. They were concerned that investigators would have difficulty understanding their obligations under the policy and under the rule and in meeting requirements of others. They called for reconciliation of any actual or apparent differences in the definitions.

A commenter urged the NIH to issue guidance to help determine whether a study is a clinical trial under the definition and to clarify how disagreements in the matter would be resolved and communicated.

Results Information Submission Timeline. A few commenters raised concerns about the proposed rule's timeline for reporting results information, asserting that 12 months after the primary completion date of the clinical trial (*i.e.,* the date of final data collection for the primary outcome measure) is too soon, particularly for NIH-funded academic investigators. These commenters suggested that academic investigators will have more difficulty meeting the timeframe because they must also spend time teaching, fulfilling clinical care responsibilities, and writing grant applications. Another commenter suggested that a 12-month timeframe would also be more challenging for academic investigators because, unlike industry investigators, they generally cannot count on support from a central administrative service to help them carry out their reporting responsibilities. Decentralization of information in academic centers would also present a particular challenge to those covered by the NIH policy, according to another commenter, who also suggested that the mobility of new investigators may make it difficult to meet timelines. These commenters urged the NIH to allow a longer submission timeframe, *e.g.,* 18 or 24 months. A few noted that providing more time would also give investigators time to prepare journal publications, and one also expressed concern about the possibility that journal editors will begin to consider submission of results information to *ClinicalTrials.gov* as prior publication, which could thwart journal publication altogether.

Structured Results Data Elements. A few commenters suggested that the data submission structure, which is determined by the provisions of the statute, does not work well for clinical trial types that will be covered only the policy, *e.g.,* phase 1 trials of drugs/biologics, small feasibility device studies, trials of social and behavioral interventions, or those with non-standard designs. These commenters thought that other fields would need to be added to the *ClinicalTrials.gov* to enable investigators to report data elements for those trials appropriately and accurately. They also suggested increasing the character limit on data fields to allow for more careful and nuanced explanations. Commenters also suggested that if the *ClinicalTrials.gov* cannot accommodate these types of trials, investigators should be exempted from the policy. One commenter requested that an additional data element should be included to allow an investigator to indicate that the trial's hypothesis had been confirmed.

Protecting Privacy. One commenter raised a concern about the policy's impact on the privacy of clinical trial participants suggesting that it might be easy to re-identify participants in many NIH-funded pilot studies with small sample sizes. The commenter pointed to the five percent threshold for non-serious adverse events and site location information as the data elements creating the vulnerability. The commenter urged the NIH to allow an investigator to obtain a waiver from results information submission where participant privacy was at risk.

Compliance Issues. The proposed policy noted that compliance with the policy would be a term and condition of award and that non-compliance may provide a basis for enforcement actions, including termination. A few commenters discussed the importance of compliance. One suggested that the NIH should take compliance records into account when considering future applications for funding. They suggested that such an approach could be more effective than terminating funding of a current grant since most of the research may already be completed. Another thought that making compliance a term and condition of award was important and that it would incentivize good behavior and help change attitudes about the value of enhancing availability of clinical trial information.

Other commenters raised concerns about the costs that will be incurred by NIH-funded academic institutions to ensure that clinical investigators are following the policy. They suggested institutions will need to provide more administrative support and other resources to help investigators comply and that this would be difficult given the indirect cost cap of 26 percent. Commenters urged the NIH to allow the time and effort required for *ClinicalTrials.gov* compliance to be included as a direct cost on NIH grants. Another commenter suggested that the increased results information submissions brought on by the NIH policy will stretch the NIH's capabilities and that it will be important for the NIH to ensure that sufficient resources are available to manage high volume data uploads and customer service requests.

NIH Policy

The NIH considered all the comments received on the proposed policy as well as those that were submitted in response to the NPRM. There was overwhelming support for both the proposed policy and the NPRM, particularly among concerned citizens, scientific societies, medical practitioners, and individual scientists. There were also concerns expressed, particularly in the comments from academic commenters. We appreciate those concerns and understand that the policy will create additional work for many investigators. However, we believe that the work should not be seen as a burden, but, rather, an inherent part of an investigator's commitment to the advancement of science. The benefits will, in the long run, accrue to the investigators as well as to the public, patients, and the enterprise as a whole because transparency will improve future research designs and maximize the public's investment—and their trust—in research. Equally important, it will help investigators fulfill the ethical obligation they have to clinical trial participants, namely to ensure that the findings from their participation contribute to generalizable knowledge and the advancement of public health.

As we noted in the preamble to the proposed policy, a fundamental premise of all NIH-funded research is that the results of such work must be disseminated in order to contribute to the general body of scientific knowledge and, ultimately, to the public health. The NIH awardees have always been expected to make the results of their activities available to the research community and to the public at large because it is intrinsic to the scientific process. In research involving human beings, moreover, scientists also have an ethical obligation to ensure that the burden and risk that volunteers assume by participating in research comes to something, at the very least by ensuring that others are aware of the study and that its findings contribute to the advancement of human health.

We disagree with commenters who suggested that there is no need for coverage of certain types of trials, such as early exploratory trials, small trials, trials assessing only safety, or trials that terminate before reaching enrollment targets. The benefits of transparency and the need to fulfill the ethical obligation to participants is as relevant to these types of trials as to any other type. We were also not persuaded that the timeframe for results information submission should be longer for academic investigators because of their competing responsibilities or that they should be allowed more time to publish their results in a journal. The timeframe of 12 months from the primary completion date should provide enough time for investigators to organize their data and submit results information. We are also confident that academic institutions can develop central support services as necessary to assist investigators should they need it. We also believe that 12 months represents an appropriate balance between investigators' interests and the interests of the public in having access to the results of a publicly funded trial. In addition, it will be possible to delay results information submission for up to two years beyond the initial deadline with a certification that regulatory approval of the trial product is being sought.

Some commenters suggested that a policy on clinical trial information dissemination is not needed because it duplicates other NIH policies. This policy is certainly in keeping with our principles, longstanding expectations, and other policies as well as the more recent broad policy call for scientific agencies to increase public access to scientific data [Ref. 5]. However, it does not duplicate any other NIH policy, nor does any other NIH policy accomplish what this one will.

Some commenters also contended that this policy is not necessary because the results of clinical trials will be published or because they can be obtained via direct requests to the trial's principal investigator. In fact, research has shown that the results of a significant portion of clinical trials are not published or published in a timely manner. For example, a 2012 study of NIH-funded clinical trials found that after a median of 51 months following trial completion, 32 percent were unpublished [Ref. 6]. A more recent study of the trial publication rate among 51 U.S. academic medical centers found that 43 percent of their clinical trials were unpublished two years after the trial was completed [Ref. 7]. While the ability to seek results information from the original investigator is useful to facilitate collaborations, to access individual-level data, and to gain insights from those who conducted the trial, it is not a surefire way to increase access to trial results nor is it efficient or transparent, particularly for the public.

We believe that the public availability of clinical trial results information will be beneficial to all parties in the long run, including those who are covered by this policy. All investigators stand to benefit from this policy. For example, science may progress more quickly because investigators will be able to learn from trials to which they otherwise would not have had access because they were unpublished. In addition, the public availability of results information helps investigators design trials and Institutional Review Boards (IRBs) review proposed trials, by allowing them to weigh the proposed study's risks and benefits against a more complete evidence base than is currently available through the scientific literature [Ref. 8]. Submission and posting of results information will also help investigators avoid repeating trials on interventions that have been found to be unsafe or unsuccessful while also providing access to information that may help verify findings.

For all of these reasons, we have not changed the essential contours of the policy. In terms of scope, the policy still applies to all NIH-funded awardees and investigators conducting clinical trials funded in whole or in part by the NIH regardless of study phase, type of intervention, or whether they are subject to the statute and to the rule. It clarifies that the policy is an expectation, that applicants and offerors are required to submit a plan outlining how they will meet the policy's expectations, and, that upon receipt of an award, an awardee will be obligated to adhere to their plan through the terms and conditions of the award. The required plan can be a brief statement explaining whether the applicant/offeror intends to register and submit results information to *ClinicalTrials.gov* as outlined in the policy or to meet the expectations in another manner. It is important to remember that an NIH-funded clinical trial that meets the definition of an applicable clinical trial is subject to the regulation and, therefore, register and submission of results information to *ClinicalTrials.gov* is a requirement.

The policy applies to both the extramural and intramural programs. For the NIH extramural program, the policy applies to applications for funding including for grants, other transactions, and contracts submitted on or after the policy's effective date that request support for the conduct of a clinical trial that is initiated on or after the policy's effective date. This means that the policy does not apply to clinical trials in ongoing, non-competing awards, but that it will apply if the grantee submits a competing renewal application that includes a new clinical trial, *i.e.*, a clinical trial initiated on or after the effective date of the policy. For the intramural program, the policy applies to clinical trials initiated on or after the policy's effective date. The policy's effective date is January 18, 2017. The policy clarifies that a clinical trial that uses NIH-supported infrastructure, but does not receive NIH funds to support its conduct, is not subject to the policy.

The policy outlines the responsibilities for NIH-funded investigators according to whether the trial is covered by the policy only or also the rule. For those covered by the policy only, NIH-funded awardees and investigators will be expected to submit the same registration and results information in the same timeframes as those subject to the statute and rule. The timeline for registration is not later than 21 calendar days after the enrollment of the first participant. The standard timeline for results information is not later than one year after the trial's primary completion date, but the policy also allows for delayed submission of results information in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval of a new use is being sought.

Although the policy does not apply to NIH-funded clinical trials initiated before the effective date, we encourage all ongoing NIH-funded clinical trials to follow it. It is also critical for investigators conducting NIH-funded applicable clinical trials that are subject to the statute and rule to be sure they are in compliance with those requirements.

The policy continues to use the NIH definition of "clinical trial" as proposed in the draft policy to determine which research studies are covered by the policy. This definition was developed in 2014 to reflect the NIH research mission and the scope of clinical trials within the NIH portfolio. With regard to the concern expressed by a public commenter that the phrase "health-related biomedical or behavioral outcomes" might be too narrow, we note that the definition considers biomedical and behavioral outcomes to be health-related outcomes in interventional studies that meet the other components of the definition. Also, regarding the concern that the wording of the definitions of clinical trial in this policy and the rule differ, this is so mainly in reference to outcomes, *i.e.,* the NIH definition explicitly references behavioral outcomes whereas the definition in the rule encompasses them within the term "health related." These distinctions are not significant in terms of defining what is covered by the NIH policy. All NIH-funded clinical trials, whether they are assessing biomedical or behavioral outcomes or whether they are employing an FDA regulated product, are covered by the policy. An NIH-funded clinical trial assessing a behavioral intervention that is not regulated by the FDA would meet both definitions of clinical trial, and, thereby, be covered by the policy. However, such a trial would not be subject to the rule because it does not meet the rule's definition of "applicable clinical trial." Guidance available on the NIH's Web site can help awardees and investigators understand whether a research study is a clinical trial for purposes of the NIH policy (see first Web site listed below). Questions should be directed to the NIH program staff. To understand whether an NIH-funded clinical trial is also subject to the statute and the rule, awardees and investigators should look to the rule's definition of "applicable clinical trial."

NIH-funded awardees and investigators will be expected to follow the provisions of the rule in terms of when they register their trials, what information they provide as part of the registration process, when they submit their results information, and what results information is submitted. All of the alternate approaches in the rule will also be available to those covered by the policy, *e.g.,* for delayed posting of device registration information, delayed submission of results information for trials involving unapproved products or products for which a new use is sought, extensions for good cause, and waivers that might be needed for privacy or national security reasons.

With regard to the concern that *ClinicalTrials.gov* is not set up to accept NIH-funded trials that are small or exploratory in nature or involve behavioral interventions, it is important to note that the *ClinicalTrials.gov* does accommodate the submission of all trial types and that a variety of study and trial types have been entered into *ClinicalTrials.gov* since its inception. In addition, *ClinicalTrials.gov* has resources available to assist investigators in navigating the registration and results information submission processes. These resources will continue to be updated over time to be responsive to investigators' needs and the evolving clinical research enterprise. Therefore, it should not be necessary for a clinical investigator of an NIH-funded clinical trial to seek an exemption from the policy for reasons related to the capacity of *ClinicalTrials.gov* to accommodate all types of clinical trials.

Registration and results information submission to *ClinicalTrials.gov* complements publication of trial results in peer-reviewed scientific journals. Information submitted to *ClinicalTrials.gov* is displayed in a structured way and includes a complete list of all pre-specified outcome measures and all adverse events. Journal articles, on the other hand, typically focus on a select set of outcome measures and adverse events and include background and discussion of the implications of the results. Information submitted to *ClinicalTrials.gov* undergoes a quality control review whereas journal articles will be peer reviewed. With regard to the concern that submission of results could make journal publication more difficult or impossible, the ICMJE has stated that submission of summary results to *ClinicalTrials.gov* will not be considered prior publication and will, thus, not interfere with journal publication [Ref. 9]. We encourage all NIH-funded investigators to publish the results of their studies in peer-reviewed journals.

We have no doubt that this policy will be beneficial for the research community as well as the public generally, but we recognize that adhering to it will be a new obligation. We will provide additional guidance to facilitate implementation and help awardees and investigators understand the policy as well as the tasks described in the rule that they will be expected to undertake. In terms of the costs of complying with the policy, grantees are permitted to charge the salaries of administrative and clerical staff as a direct cost [Ref. 10]. Such staff could assist investigators in meeting their responsibilities under the policy. In addition, administrative costs can be covered through indirect cost recovery.

We intend for this policy to benefit all communities who seek information about NIH-funded clinical trials, and we are confident that the benefits of transparency will become evident soon after the policy is implemented. We plan to evaluate the implementation and impact of the policy from the perspective of those who comply with it as well as from the perspective of *ClinicalTrials.gov* users, including patients, providers, and investigators.

We look forward to engaging with NIH-funded investigators and awardees as they work to meet the expectations of this important public policy. Information to assist applicants, offerors, and investigators is available at the following Web sites. The NIH will continue to add guidance materials to these sites as the policy's implementation continues.

- *http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials*
- *https://clinicaltrials.gov/ct2/manage-recs*
- *http://grants.nih.gov/clinicaltrials_fdaaa/faq.htm*

The NIH policy is set forth below.

References

1. National Institutes of Health, U.S. Department of Health and Human Services, NIH request for public comments on the proposed NIH policy on dissemination of NIH-funded clinical trial information. NIH Guide for Grants and Contracts. 2014 Nov 19. Available from *https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-019.html.* Also published in Fed Regist. 2015 Feb 13; 80(30):8096–98. Available from *https://www.federalregister.gov/articles/2015/02/13/2015-02994/announcement-of-a-draft-nih-policy-on-dissemination-of-nih-funded-clinical-trial-information.*
2. National Institutes of Health, U.S.

Department of Health and Human Services, Notice of Proposed Rulemaking on Clinical Trials Registration and Results Submission. Fed Regist. 2014 Nov 21;79(225):69566–69680. Available from *https://www.federalregister.gov/articles/2015/02/13/2015-02990/clinical-trials-registration-and-results-submission.*

3. A compilation of public comments on the draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information is available at: *http://osp.od.nih.gov/sites/default/files/resources/Clinical%20Trials%20Dissemination%20Policy%20Combined%20Comments_2.0.pdf.*
4. U.S. Department of Health and Human Services, National Institutes of Health, National Library of Medicine. Clinical Trials Registration and Results Submission. [Internet]. 2011 [cited 2016 September 1]. Available from: *https://www.regulations.gov/docket?D=NIH-2011-0003.*
5. NIH Data Sharing Policy (*https://grants.nih.gov/grants/policy/data_sharing/*); NIH Public Access Policy (*https://publicaccess.nih.gov/policy.htm* or *https://publicaccess.nih.gov/*); NIH Genomic Data Sharing Policy (*https://gds.nih.gov/03policy2.html*); Increasing Access to the Results of Federally Funded Scientific Research (*https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf*).
6. Ross et al., BMJ. 2012 Jan 3;344:d7292. *http://www.bmj.com/content/bmj/344/bmj.d7292.full.pdf.*
7. Chen et al., BMJ. 2016 Feb 17;352:i637 *http://www.bmj.com/content/bmj/352/bmj.i637.full.pdf.*
8. Berlin, JA, et al., Bumps and Bridges on the Road to Responsible Sharing of Clinical Trial Data. Clinical Trials. 2014;11:7–12.
9. ICMJE [Internet]. International Committee of Medical Journal Editors; 2016. Clinical trial registration; 2011 [cited 2016 Aug 5]; [about 2 screens]. Available from: *http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html* and *http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/.*
10. 45 CFR 75.413(c) and Chapter 8.1.1.6, Direct Charging Salaries of Administrative and Clerical Staff. NIH Grants Policy Statement. *http://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1_changes_in_project_and_budget.htm.*

NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

Purpose

The National Institutes of Health (NIH) Policy on Dissemination of NIH-funded Clinical Trial Information establishes the expectation that all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by the NIH, will ensure that their NIH-funded clinical trials are registered at, and that summary results information is submitted to, *ClinicalTrials.gov* for public posting.[1] The purpose of the policy is to promote broad and responsible dissemination of information from NIH-funded clinical trials through *ClinicalTrials.gov.* Disseminating this information supports the NIH mission to advance the translation of research results into knowledge, products, and procedures that improve human health.

This policy is complementary to requirements in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR part 11, hereinafter referred to as the regulation.[2] Clinical trials that are subject to the regulation are, in general, clinical trials of drug, biological, and device products regulated by the Food and Drug Administration (FDA), except phase 1 trials of drug and biological products and small feasibility studies of device products. A pediatric post-market surveillance study of a device product required by the FDA is also subject to the regulation. Clinical trials subject to the regulation are generally called "applicable clinical trials." Applicable clinical trials are required to be registered in *ClinicalTrials.gov* not later than 21 calendar days after the enrollment of the first participant. Results information from those trials generally must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of a new use is being sought.

Scope and Applicability

This policy applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions. As such, the policy encompasses all NIH-funded clinical trials, including applicable clinical trials subject to the regulation. All NIH-funded clinical trials will be expected to register and submit results information to *ClinicalTrials.gov.*

This policy applies to clinical trials funded in whole or in part through the NIH extramural and intramural programs. For the NIH extramural program, the policy applies to applications for funding including for grants, other transactions, and contracts submitted on or after the policy's effective date that request support for the conduct of a clinical trial that is initiated on or after the policy's effective date. For the NIH intramural program, the policy applies to clinical trials initiated on or after the policy's effective date.

This policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.

Responsibilities

As part of their applications or proposals, applicants and offerors seeking NIH funding will be required to submit a plan for the dissemination of NIH-funded clinical trial information that will address how the expectations of this policy will be met. NIH-funded awardees and investigators conducting clinical trials funded in whole or in part by the NIH will be required to comply with all terms and conditions of award, including following their plan for the dissemination of NIH-funded clinical trial information.

Consistent with those terms and conditions, the responsibilities of such awardees and investigators will fall within one of the three categories. The category depends on whether, under the regulation, the clinical trial is also an "applicable clinical trial" and the awardee or investigator is the "responsible party."

1. If the NIH-funded clinical trial *is* an applicable clinical trial under the regulation and the awardee or investigator *is* the responsible party, the awardee or investigator will ensure that all regulatory requirements are met.

2. If the NIH-funded clinical trial *is* an applicable clinical trial under the regulation but the awardee or investigator *is not* the responsible party, the awardee or investigator will coordinate with the responsible party to ensure that all regulatory requirements are met.

3. If the NIH-funded clinical trial *is not* an applicable clinical trial under the regulation, the awardee or investigator will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in *ClinicalTrials.gov* and submitting results information to *ClinicalTrials.gov.*

---

[1] *ClinicalTrials.gov* is operated by the National Library of Medicine within the NIH.

[2] The Clinical Trial Registration and Results Information Submission regulation at 42 CFR part 11 was issued in the **Federal Register** in September 2016. The regulation implements section 402(j) of the Public Health Service Act.

In addition, informed consent documents for clinical trials within all three categories are to include a specific statement relating to posting of clinical trial information at *ClinicalTrials.gov.*

Each NIH-funded clinical trial should have only one entry in *ClinicalTrials.gov* that contains its registration and results information. Awardees and investigators need not and should not create a separate record of the applicable clinical trial to comply with this policy.

The NIH will publicly post registration information and results information in *ClinicalTrials.gov.*

Definitions

Clinical Trial. For purposes of this policy, a "clinical trial" means "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." [3] This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, *e.g.,* behavioral interventions. This definition of "clinical trial" [4] is broader than the term "applicable clinical trial" as defined in the regulation.[5]

Responsible Party. In the policy, the awardee or the investigator is responsible for meeting the expectations of this policy. In the regulation, a "responsible party" means, in part, "with respect to a clinical trial, the sponsor of the clinical trial, as defined in 21 CFR 50.3 (or any successor regulation); or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under [42 CFR part 11] for the submission of clinical trial information." [6]

Primary Completion Date. In the policy, this term has the same meaning as the term "primary completion date" in the regulation, which is "the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated." [7]

Registration Information. In the policy, this term has the same meaning as the term "registration information" in the regulation. In the regulation, registration information consists of descriptive information, recruitment information, location and contact information, and administrative data.[8]

Results Information. In the policy, this term has the same meaning as the term "results information" in the regulation. In the regulation, results information includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information.[9]

Compliance

If the clinical trial is NIH-funded in whole or in part, expectations for clinical trial registration and summary results submission will be included in the terms and conditions of the award. Failure to comply with the terms and conditions of the NIH award may provide a basis for enforcement actions, including termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 U.S.C. 282(j) and 42 CFR part 11 may also lead to the actions described in 42 CFR 11.66.

Effective Date

This policy is effective January 18, 2017.

Date: September 12, 2016.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2016–22379 Filed 9–16–16; 11:15 am]

BILLING CODE 4140–01–P

---

[3] Further information about this definition is available from the NIH Office of Science Policy at *http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials.*

[4] Note that the regulation also includes a definition of "clinical trial." That definition is "a clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health related outcomes" (*see* 42 CFR 11.10 (a)). For the purposes of this policy, the regulatory definition and the definition in this policy are treated as synonymous.

[5] In the regulation, applicable clinical trial is defined as an applicable device clinical trial or an applicable drug clinical trial. The regulation defines an applicable device clinical trial to mean, in part, "a prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes)." The regulation defines an applicable drug clinical trial to mean, in part, "a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 (or any successor regulation) and "phase 1" has the meaning given in 21 CFR 312.21 (or any successor regulation)."

[6] See 42 CFR 11.10 (a) and 42 CFR 11.4.

[7] See the complete definition at 42 CFR 11.10 (a).

[8] See 42 CFR 11.10 (b) and 42 CFR 11.28 for the specific data elements.

[9] See 42 CFR 11.28 for complete results information and specific data elements.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; TRND2.

Date: October 13, 2016.

Time: 11:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Room 1087, 6701 Democracy Blvd., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Director, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1080, Bethesda, MD 20892–4878, 301–451–2405, *henriquv@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 15, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22669 Filed 9–20–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5915–N–10]

60-Day Notice of Proposed Information Collection: Small Area Fair Market Rent Demonstration Evaluation

AGENCY: Office of Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* November 21, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone (202) 402–5534 (this is not a toll-free number) or email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone (202) 402–5535. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Small Area Fair Market Rent Demonstration Evaluation.

OMB Approval Number: N/A.

Type of Request: New.

Description of the need for the information and proposed use: HUD generally publishes a single FMR for each metropolitan area and provides public housing agencies with discretion to vary local voucher payment standards between 90 and 110 percent of the Fair Market Rent (FMR) (unless HUD approves an exception). The SAFMR demonstration is testing the alternative approach of setting FMRs at the ZIP Code level. The core hypothesis is that this will significantly expand the ability of Housing Choice Vouchers (HCV) holders to access housing in neighborhoods with high-quality schools, low crime rates, and other indicators of opportunity, as well as integrated neighborhoods in furtherance of HUD's goal of affirmatively furthering fair housing.

HUD is evaluating the SAFMR demonstration and an important consideration in this evaluation is how voucher holders and landlords perceive the shift from traditional area-wide FMRs to SAFMRs. HUD will look into whether both existing and new voucher holders understood how the change to using SAFMRs affected their housing options and whether it led movers to search in new neighborhoods or affected the rate of moving of existing voucher holders. Similarly, HUD wants to know whether landlords were aware of the change in the HCV program and whether this affected their willingness to rent to voucher holders and the level at which they set rents. In order to address these perceptions, 70 tenants and 35 landlords will be interviewed in the areas served by the five PHAs that are in the SAFMR demonstration: Housing Authority of Cook County (IL); Housing Authority of the City of Long Beach (CA); Chattanooga (TN) Housing Authority; Town of Mamaroneck (NY) Housing Authority; Housing Authority of the City of Laredo (TX); and two PHAs from the Dallas metropolitan area—Dallas Housing Authority (TX), and the Plano Housing Authority (TX). To build rapport during recruitment, by acknowledging the value of their time, an incentive payment of $20 for tenants and $40 for landlords will be made.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Cost per response	Annual cost
Tenants	70	1	1	0.5	35	$20	$1,400
Landlords	35	1	1	1	35	40	1,400
Total	105				70		2,800

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: September 8, 2016.

Katherine M. O'Regan,

Assistant Secretary, Office of Policy Development and Research.

[FR Doc. 2016–22722 Filed 9–20–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5910–N–12]

60–Day Notice of Proposed Information Collection: Public Comment Request: Notice on Equal Access Regardless of Sexual Orientation, Gender Identity, or Marital Status for HUD's Community Planning and Development Programs

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act (PRA), HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* November 21, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the notice.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Persons who are deaf or hard of hearing or have speech impairments may access this number via TTY by calling the toll-free Federal Relay Service at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Norm Suchar, Director, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410–7000; telephone number 202–708–4300 (this is not a toll-free number). Persons who are deaf or hard of hearing or have speech impairments can access this number via TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

As noted in the Summary, elsewhere in today's **Federal Register**, HUD is publishing its final rule entitled "Equal Access in Accordance with an Individual's Gender Identity in Community Planning and Development Programs." Through this final rule, HUD ensures equal access to individuals in accordance with their gender identity in programs and shelter funded under programs administered by HUD's Office of Community Planning and Development (CPD). This rule builds upon HUD's February 2012 final rule entitled "Equal Access to Housing in HUD Programs Regardless of Sexual Orientation or Gender Identity" (2012 Equal Access Rule), which aimed to ensure that HUD's housing programs would be open to all eligible individuals and families regardless of sexual orientation, gender identity, or marital status. The 2012 Equal Access Rule, however, did not address how transgender and gender non-conforming individuals should be accommodated in temporary, emergency shelters and other buildings and facilities used for shelter that have physical limitations or configurations that require and that are permitted to have shared sleeping quarters or shared bathing facilities.[1] This final rule published in today's **Federal Register** follows HUD's November 20, 2015 proposed rule, which addressed this issue after soliciting public comment. The final rule requires that recipients and subrecipients of CPD funding, as well as owners, operators, and managers of shelters, and other buildings and facilities and providers of services funded in whole or in part by any CPD program to grant equal access to such facilities, and other buildings and facilities, benefits, accommodations and services to individuals in accordance with the individual's gender identity, and in a manner that affords equal access to the individual's family.

The notice set out in the appendix presents an additional measure by HUD to ensure that individuals seeking placement or accommodation in a shelter or other building or facility and housing funded under a program administered by CPD are aware of HUD's equal access policy, as established in HUD's 2012 Equal Access Rule, and elaborated upon in the final rule published in today's **Federal Register**. Through this PRA notice, HUD proposes to require owners and operators of CPD-funded shelters, housing, buildings and other facilities to post this notice on bulletin boards and in other public places where individuals staying in the shelter, building, housing or facility or seeking placement or accommodation in the shelter, building, housing, or facility would see this information. HUD strives to reduce burden by providing the content of the notice to be posted and estimates it will take about six minutes for owners and operators to print and post this notice. All existing and new owners would be required to post the notice only once, and ensure that it remains visible to those accessing the shelter, housing, or facility.

---

[1] Shared sleeping quarters and shared bathing facilities are those for simultaneous use by more than one person.

II. Overview of Information Collection

Title of Proposal: Notice on Equal Access Regardless of Sexual Orientation, Gender Identity, or Marital Status for HUD's Community Planning and Development Programs.

OMB Control Number, if applicable: 2506–new.

Description of the need for the information and proposed use: As noted above, the purpose of the notice set out in the appendix to this PRA notice is to ensure that individuals seeking placement or accommodation in a shelter, building, housing or facility funded under a program administered by CPD are aware of HUD's equal access requirements, as established in HUD's 2012 Equal Access Rule, and elaborated upon in the final rule published in today's **Federal Register.**

Agency form numbers, if applicable: Not applicable.

Members of affected public. Owners and operators of a shelter, building, housing or facility funded under programs administered by CPD.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: Please see table below.

REPORTING AND RECORDKEEPING BURDEN

Information collection A	Number of respondents * B	Response frequency (average) C	Total ** responses D	Burden hours per response E	Total annual hours F	Hourly rate ***	Burden cost per instrument
HOME Investment Partnerships program	25,350	1	25,350	.10	2535	21.73	$55,085
Community Development Block Grant program (State and Entitlement)	2430	1	2430	.10	243	21.73	5,280
Housing Opportunities for Persons with AIDS program	100	1	100	.10	10	21.73	217
Emergency Solutions Grants program & Continuum of Care ...	6,750	1	6,750	.10	675	21.73	14,667
Total	34,630	....	34,630	....	3,463	....	75,249

* No response is required—only the public posting of the notice within the facility.

** This is a one-time burden and does not need to be reposted annually, so long as the original posting remains intact.

*** Annualized Cost @$21.73/hr (Rate for a Social Worker in Individual Family and Services. *http://www.bls.gov/oes/current/oes211029.html.*

II. Solicitation of Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: September 14, 2016.

Harriet Tregoning,

Principal Deputy Assistant Secretary for Community Planning and Development.

Appendix

Notice on Equal Access Regardless of Sexual Orientation, Gender Identity, or Marital Status for HUD's Community Planning and Development Programs

This [shelter/building/housing/facility] receives funding from the U.S. Department of Housing and Urban Department's (HUD) Office of Community Planning and Development (CPD) and MUST comply with the following REQUIREMENTS:

- Determine your eligibility for housing regardless of your sexual orientation, gender identity, or marital status, and must not discriminate against you because you do not conform to gender or sex stereotypes (*i.e.*, because of your gender identity);
- Grant you equal access to CPD programs or facilities consistent with your gender identity, and provide your family with equal access;
- MUST NOT ask you to provide anatomical information or documentary (like your ID), physical, or medical evidence of your gender identity; and
- Take non-discriminatory steps when necessary and appropriate to address privacy concerns raised by any residents or occupants, including you.

If you think this program has violated any of these requirements, including any denial of services or benefits, contact your *local HUD office* for assistance with alleged violations of HUD program regulations. Local offices can be found at: *http://portal.hud.gov/hudportal/HUD?src=/program_offices/field_policy_mgt/localoffices*

If you believe you have experienced housing discrimination because of race, color, religion, national origin, disability, or sex, including discrimination because of gender identity, contact 1–800–669–9777 or file a written complaint with HUD at: *www.hud.gov* "file a discrimination complaint". Persons who are deaf, hard of hearing, or have speech impairments may file a complaint via TTY by calling the Federal Information Relay Service at (800) 877–8339.

To better understand HUD's requirements, the following definitions apply:

- *Sexual orientation* means one's emotional or physical attraction to the same and/or opposite sex (*e.g.* homosexuality, heterosexuality, or bisexuality).
- *Gender identity* means the gender with which a person identifies, regardless of the sex assigned to that person at birth and regardless of the person's perceived gender identity.
- *Perceived gender identity* means the gender with which a person is perceived to

identify based on that person's appearance, behavior, expression, other gender related characteristics, or sex assigned to the individual at birth or identified in documents.

[FR Doc. 2016–22587 Filed 9–20–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5969–N–01]

Eligibility of Independent Students for Assisted Housing Under Section 8 of the U.S. Housing Act of 1937; Additional Supplementary Guidance

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, and Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: On December 30, 2005, HUD published a final rule (FR–5036–F–01), "Eligibility of Students for Assisted Housing under Section 8 of the U.S. Housing Act of 1937", implementing section 327 of the agency's Fiscal Year 2006 appropriations, Title III of Public Law 109–115, 119 Stat. 2936, approved November 30, 2005 (2006 HUD Appropriations Act). Section 327 requires that if an individual is enrolled at an institution of higher education (*i.e.,* student) is under the age of 24, is not a veteran, is unmarried and does not have a dependent child, is individually ineligible for assistance under section 8 of the United States Housing Act of 1937 (section 8 assistance), or the student's parents are, individually or jointly, ineligible for assistance, no section 8 assistance can be provided to the student.

On April 10, 2006, HUD published supplemental guidance to assist providers in implementing the final rule. That supplemental guidance provided a list of items that Public Housing Agencies, Owners, and Managers are required to verify when determining whether a student's income alone should be used to determine section 8 eligibility, and this notice updates that list of items to remain consistent with the U.S. Department of Education's definition of "independent student," and reduce barriers for vulnerable youth to receive assistance and continue their education.

FOR FURTHER INFORMATION CONTACT: Rebecca L. Primeaux, Director, Housing Voucher Management and Operations Division, Office of Public and Indian Housing, Room 4214, U.S. Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410–8000, telephone (202) 402–6050 (this is not a toll-free number), or Danielle D. Garcia, Branch Chief, Multifamily Housing, Assisted Housing Oversight Division, Room 6148, U.S. Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410–8000, telephone (202) 402–2768 (this is not a toll-free number). Persons with hearing or speech impairments may access these numbers through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION

I. Background

Section 327 of HUD's Fiscal Year 2006 appropriations, Title III of Public Law 109–115, 119 Stat. 2936, approved November 30, 2005 (2006 HUD Appropriations Act), introduced new restrictions on providing housing assistance to students of higher education under section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f) (1937 Act). On December 30, 2005, at 70 FR 77742, HUD published a final rule implementing section 327 of the Act (Section 327) in accordance with the statutory requirement that HUD issue a final rule no later than 30 days following enactment of the 2006 HUD Appropriations Act. HUD's rule implementing the statute prohibits section 8 assistance to an individual who is enrolled at an institution of higher education (*i.e.,* students), is under the age of 24, is not a veteran, is unmarried, does not have a dependent child, and is individually ineligible for section 8 assistance or has parents who are, individually or jointly, ineligible on the basis of income to receive assistance.

On April 10, 2006, at 71 FR 18146, HUD issued supplementary guidance to further assist Public Housing Agencies (PHAs) and multifamily project owners and management agents (Owners and Managers) with the implementation of the new eligibility restrictions (2006 supplementary guidance). HUD's 2006 supplementary guidance provided certain exceptions to the requirement that the eligibility of a student seeking section 8 assistance would be determined based on income eligibility for the assistance by both the student and the student's parents. HUD's 2006 supplementary guidance explained that a student, under the age of 24 who meets the additional criteria of Section 327, may still be income eligible for assistance in circumstances where the student can demonstrate independence from parents, where the student can demonstrate the absence of parents, or where an examination of the student's parents' income may not be relevant. The 2006 supplementary guidance instructs PHAs, Owners, and Managers to consider certain criteria, including but not limited to, whether:

(1) The individual is of legal contract age under state law.

(2) The individual has established a household separate from parents or legal guardians for at least one year prior to application for occupancy or the individual meets the U.S. Department of Education's definition of an "independent student." Section 480(d) of the Higher Education Act of 1965, as amended (the HEA), 20 U.S.C. 1087vv(d).

(3) The individual is not claimed as a dependent by parents or legal guardians pursuant to IRS regulations.

(4) The individual obtains a certification of the amount of financial assistance that will be provided by parents, signed by the individual providing the support, even if no assistance will be provided.

The 2006 supplemental guidance also provided a list of items that PHAs, Owners, and Managers must verify to determine whether a student is independent for purposes of using the student's income alone for determining Section 8 eligibility (Student's Independence Verification Requirements). Those items include:

(1) Previous address information to determine evidence of a separate household, or verifying the student meets the U.S. Department of Education's definition of "independent student";

(2) prior year income tax returns to verify if a parent or guardian has claimed the student as a dependent, except if the student meets the Department of Education definition of "independent student"; and

(3) written certification by a parent of the amount of financial support that parent provides to the student, or written certification that the parent provides no financial support to the student.

HUD also adopted in Appendix A of the 2006 supplementary guidance the U.S. Department of Education's (ED) definition of "independent student" from the HEA. ED's definition provided that an "independent student" is a student who meets one or more of the following criteria: (a) Is at least 24 years old by December 31 of the award year for which aid is sought; (b) is an orphan or a ward of the court through the age of 18; (c) is a veteran of the United States Armed Forces; (d) has legal dependents other than a spouse (for example, dependent children or an elderly dependent parent); (e) is a graduate or professional student; or, (f) is married.[1]

In 2007, the HEA definition was amended and expanded in Section 604 of the College Cost Reduction and Access Act of 2007 (Public Law 110–84, 121 Stat. 784, approved September 27, 2006). The College Cost Reduction and Access Act added new criteria to the definition of "independent student" to include broadening the category of students who were orphans or wards of the court at age 18 to include those who were orphans, in foster care, or were wards of the court at any time when the individual was 13 years of age or older; it added those students who are or were emancipated or in legal guardianship; and added unaccompanied youths who are homeless or who are at risk of homelessness. This new definition was adopted by ED in guidance.

II. Definition of "Independent Student"

This notice brings HUD's guidance into conformity with the updated HEA definition and ED's definition of "independent student." ED's definition of "independent student" is one of the criteria in HUD's 2006 supplementary guidance for PHAs, owners and managers to use in verifying whether a student is "independent." Specifically, HUD is updating the definition of "independent student" to include the more expansive definition found in HEA, as amended by the College Cost Reduction and Access Act of 2007.

ED's definition of "independent student", which now applies is:

a. The individual is 24 years of age or older by December 31 of the award year;

b. The individual is an orphan, in foster care, or a ward of the court or was an orphan, in foster care, or a ward of the court at any time when the individual was 13 years of age of older;

c. The individual is, or was immediately prior to attaining the age of majority, an emancipated minor or in legal guardianship as determined by a court of competent jurisdiction in the individual's State of legal residence;

d. The individual is a veteran of the Armed Forces of the United States (as defined in subsection (c)(1) of HEA) or is currently serving on active duty in the Armed Forces for other than training purposes;

e. The individual is a graduate or professional student;

f. The individual is a married individual;

g. The individual has legal dependents other than a spouse;

h. The individual has been verified during the school year in which the application is submitted as either an unaccompanied youth who is a homeless child or youth (as such terms are defined in section 725 of the McKinney-Vento Homeless Assistance Act) (42 U.S.C. 11431 *et seq.*), or as unaccompanied, at risk of homelessness, and self-supporting, by—

(i) a local educational agency homeless liaison, designated pursuant to section 722(g)(1)(J)(ii) of the McKinney-Vento Homeless Assistance Act;

(ii) the director of a program funded under the Runaway and Homeless Youth Act or a designee of the director;

(iii) the director of a program funded under subtitle B of title IV of the McKinney-Vento Homeless Assistance Act (relating to emergency shelter grants) or a designee of the director; or

(iv) a financial aid administrator; or

i. The individual is a student for whom a financial aid administrator makes a documented determination of independence by reason of other unusual circumstances.[2]

III. Student's Independence Verification Requirements

HUD is also amending the Student's Independence Verification Requirements set out in the 2006 supplementary guidance. These requirements may create barriers for youth, and especially vulnerable youth (*i.e.,* unaccompanied homeless youth, at risk of being homeless youth, and youth who have aged out of foster system), to receive assistance and continue their education, as many of these youth are not connected to their parents or caregivers to obtain the information necessary to show they are "independent" under HUD's current guidance. Therefore, HUD is clarifying that the tax return requirement only applies to providing the student's tax returns and not that of the student's parents.

HUD also provides through this guidance that an individual who meets ED's "independent student" definition in paragraph (b), (c), or (h), as adopted in Section II of this notice, are considered "vulnerable youth" for purposes of this guidance, and provides that when a PHA, owner or manager determines an individual is a "vulnerable youth" such determination is all that is necessary to determine a person is an "independent student" for purposes of using only the student's income for determining eligibility for section 8 assistance. The new Student's Independence Verification Requirements are as follows:

PHAs, Owners, and Managers of section 8 assistance will need to verify a student's independence from his or her parents to determine that the student's parents' income is not relevant for determining the student's eligibility for assistance by doing all of the following:

(1) Reviewing and verifying previous address information to determine evidence of a separate household or verifying the student meets the U.S. Department of Education's definition of "independent student";

(2) Reviewing a student's prior year income tax returns to verify the student is independent or verifying the student meets the U.S. Department of Education's definition of "independent student"; and

(3) Verifying income provided by a parent by requiring a written certification from the individual providing the support. Certification is also required if the parent is providing no support to the student. Financial assistance that is provided by persons not living in the unit is part of annual income. (Except if the student meets the Department of Education's definition of "independent student" in paragraphs (b), (c) or (h) adopted in section II of this notice).

This guidance and HUD's rule focus on a student under the age of 24 who meets the additional requirements of section 327 and who is not residing in a section 8 assisted unit with his or her parents, but who is individually seeking to reside in a section 8 assisted unit. Neither the rule nor this guidance applies to students residing with their parents in a section 8 assisted unit or who reside with parents who are applying to receive section 8 assistance.

Dated: September 16, 2016.

Lourdes Castro Ramirez,

Principal Deputy Assistant Secretary for Public and Indian Housing.

Edward L. Golding,

Principal Deputy Assistant Secretary for Housing.

[FR Doc. 2016–22727 Filed 9–20–16; 8:45 am]

BILLING CODE 4210–67–P

---

[1] The Higher Education Act of 1965. 20 U.S.C. 1087vv(d). See also Jeffrey R. Andrade, "Dear Colleague" Letter, U.S. Dep't of Educ. (May 2, 2003), *https://ifap.ed.gov/dpcletters/GEN0307.html.*

[2] These letters reflect the numbering used in the HEA definition of "independent" for use in this notice.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5910–N–15]

60-Day Notice of Proposed Information Collection: Disaster Recovery Grant Reporting System

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* November 21, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone (202) 402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Jessie Handforth Kome, Acting Director, Office of Block Grant Assistance, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410 at (202) 708–3587. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Disaster Recovery Grant Reporting System.

OMB Approval Number: 2506–0165.

Type of Request: Extension of currently approved collection.

Form Number: SF–424 Application for Federal Assistance.

Description of the need for the information and proposed use: Disaster Recovery Grant Reporting (DRGR) System is a grants management system used by the Office of Community Planning and Development to monitor special appropriation grants under the Community Development Block Grant program. This collection pertains to Community Development Block Grant Disaster Recovery (CDBG–DR), Neighborhood Stabilization Program (NSP), Rural Capacity Building (RCB) for Community Development, and Affordable Housing Capacity Building for Affordable Housing and Community Development Program (Section 4 program) grant appropriations.

The CDBG program is authorized under Title I of the Housing and Community Development Act of 1974, as amended. Following major disasters, Congress appropriates supplemental CDBG funds for disaster recovery. According to Section 104(e)(1) of the Housing and Community Development Act of 1974, HUD is responsible for reviewing grantees' compliance with applicable requirements and their continuing capacity to carry out their programs. Grant funds are made available to states and units of general local government, Indian tribes, and insular areas, unless provided otherwise by supplemental appropriations statute, based on their unmet disaster recovery needs.

The Rural Capacity Building (RCB) Program enhances the capacity and ability of local governments, Indian tribes, housing development organizations, rural Community Development Corporations (CDCs), and rural Community Housing Development Organizations (CHDOs), to carry out community development and affordable housing activities that benefit low- and moderate-income families and persons in rural areas. The original authorizing statute for the RCB program is the Consolidated and Further Continuing Appropriations Act, 2012, Public Law 112–55.

The Capacity Building for Affordable Housing and Community Development Program, also known as the Section 4 program, was originally authorized under Section 4 of the HUD Demonstration Act of 1993 (Pub. L. 103–120, 107 Stat. 1148, 42 U.S.C. 9816 note), as amended. The program enhances the capacity and ability of community development corporations (CDCs) and community housing development organizations (CHDOs) to carry out community development and affordable housing activities that benefit low-income persons.

Respondents: DRGR is used to monitor CDBG–DR, NSP, NSP–TA, RCB and Section 4 grants, as well as several programs that do not fall under the Office of Block Grant Assistance. Separate information collections have been submitted and approved for these programs. CDBG–DR and NSP grant funds are made available to states and units of general local government, Indian tribes, and insular areas, unless provided otherwise by supplemental appropriations statute. NSP–TA grant funds are awarded on a competitive basis and are open to state and local governments, as well as non-profit groups and consortia that may include for-profit entities. RCB grants are competitively awarded to local governments, Indian tribes, housing development organizations, rural Community Development Corporations (CDCs), and rural Community Housing Development Organizations (CHDOs). Section 4 grant funds are directly awarded to grantees designated in the authorizing statute and subsequent appropriations.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
CDBG–DR Non-Recurring							
Published Action Plan	7	1	7	40	280	$25	$7,000
SF 424	7	1	7	1	7	25	175
Procurement, Financial Controls and DOB documentation.	7	1	7	6	42	25	1,050
Performance and Financial Projections	7	1	7	8	56	25	1,400
Grant Agreement (HUD 40092)	7	1	7	40	280	25	7,000
Grantee's Written Agreements	7	1	7	1	7	25	175

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
DRGR Activation, Activity Set-Up and Completion.	7	1	7	6	42	25	1,050
CDBG–DR Recurring							
Average Sized Grants Online Quarterly Reporting via DRGR.	20	1	20	1	20	25	500
Large Grants Online Quarterly Reporting via DRGR.	20	1	20	5	100	25	2,500
Average-sized grants online voucher submissions.	20	1	20	20	400	25	10,000
Large-sized grants online voucher submission.	20	1	20	1	20	25	500
CDBG–DR Subtotal	134	1,023	31,420	N/A	20,821	25	520,527
NSP Recurring							
Online Quarterly Reporting via DRGR	617	4	2,468	4	9,872	25	246,800
DRGR voucher submissions	617	38	23,446	0.18	4,220	25	105,507
NSP Subtotal	617	42	25,914	N/A	14,092	N/A	352,307
NSP3–TA Recurring							
TA work plan submissions	12	5	60	8	480	25	12,000
DRGR voucher submissions	12	38	456	0.18	82	25	2,052
NSP3–TA Subtotal	12	43	516	N/A	562	N/A	14,052
Rural Capacity and Section 4 Non-Recurring							
DRGR Activation and Account Setup	8	1	8	2	16	35	960
Action Plan Setup and Submission	8	1	8	12	96	35	5,760
Rural Capacity and Section 4 Recurring							
Action Plan Revisions	16	2	32	0.5	16	35	560
Semi-Annual Report Submission	16	2	32	8	256	35	8,960
Voucher Submission	16	12	192	0.25	48	35	1,680
RCB and Section 4 Subtotal	16	18	272	N/A	592	N/A	15,120
Total	779	1,126	58,122	N/A	36,067	Varies	902,006

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: September 14, 2016.

Harriet Tregoning,

Principal Assistant Secretary for Community Planning and Development.

[FR Doc. 2016–22719 Filed 9–20–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167 A2100DD/AAKC001030/A0A501010.999900]

Indian Gaming; Approval of a Tribal-State Class III Gaming Compact in the State of South Dakota

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Flandreau Santee Sioux Tribe of South Dakota and State of South Dakota entered into a compact replacing and superseding an existing Tribal-State compact governing Class III gaming; this notice announces approval of the compact.

DATES: Effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Assistant Secretary—Indian Affairs, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Section 11 of the Indian Gaming Regulatory Act (IGRA) requires the Secretary of the Interior to publish in the **Federal Register** notice of approved Tribal-State compacts that are for the purpose of engaging in Class III gaming activities on Indian lands. *See* Public Law 100–497, 25 U.S.C. 2701 *et seq.* All Tribal-State Class III compacts, including amendments, are subject to review and approval by the Secretary under 25 CFR 293.4. The compact increases the authorized number of gaming machines to 1,000, and establishes Tribal contributions to local governments based on the number of gaming machines in operation. In addition, the term of the compact is subject to review at 10 year intervals, starting from the date of approval of this compact, with an automatic 10 year renewal. The compact is approved. *See* 25 U.S.C. 2710(d)(8)(A).

Dated: September 13, 2016.

Lawrence S. Roberts,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2016–22649 Filed 9–20–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[16X LLAK910000.L13100000.DB0000. LXSINSSI0000]

Notice of Public Meeting, North Slope Science Initiative—Science Technical Advisory Panel

AGENCY: Bureau of Land Management Alaska, North Slope Science Initiative, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act, the U.S. Department of the Interior, North Slope Science Initiative (NSSI)—Science Technical Advisory Panel (STAP) will meet as indicated below.

DATES: The meeting will be held October 6 and 7, 2016, in Anchorage, Alaska. The meeting will be held in the Training Room at the Bureau of Land Management, Anchorage District Office, 4700 BLM Road, Anchorage, Alaska 99507. On Thursday October 6, the meeting will begin at 9 a.m. and end at 4:30 p.m., and on Friday October 7, it will begin at 9 a.m. and end at 3:30 p.m. There will be an opportunity for public comment on Thursday, October 6 from 4–4:30 p.m. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited.

FOR FURTHER INFORMATION CONTACT: Scott Guyer, Acting Deputy Director, North Slope Science Initiative, Bureau of Land Management, 222 W. Seventh Avenue, #13, Anchorage, AK 99513, (907) 271–3284 or email *sguyer@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The NSSI STAP provides advice and recommendations to the NSSI Oversight Group regarding priority information needs for management decisions across the North Slope of Alaska. These priority information needs may include recommendations on inventory, monitoring, and research activities that contribute to informed resource management decisions. This meeting will include discussion and prioritization of recommendations from the scenario development project, emerging issues papers and the May 2016 Barrow Workshop. Individuals who plan to attend and need special assistance, such as sign language interpretation, transportation, or other reasonable accommodations, should contact the Acting NSSI Deputy Director. The public may present written comments to the STAP through the NSSI Acting Deputy Director. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Steve Cohn,

Acting State Director.

[FR Doc. 2016–22701 Filed 9–20–16; 8:45 am]

BILLING CODE 4310–JA–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1021]

Certain Personal Transporters and Components Thereof Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on August 16, 2016, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Segway Inc. of Bedford, New Hampshire; DEKA Products Limited Partnership of Manchester, New Hampshire; and Ninebot (Tianjin) Technology Co., Ltd. of China. A supplement to the complaint was filed on September 2, 2016. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain personal transporters and components thereof by reason of infringement of U.S. Patent No. 6,302,230 (“the ’230 patent”) and U.S. Patent No. 7,275,607 (“the ’607 patent”). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue a general exclusion order, or in the alternative a limited exclusion order, and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission’s Rules of Practice and Procedure, 19 CFR 210.10 (2016).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on September 15, 2016, *Ordered That*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain personal transporters and components thereof by reason of infringement of one or more of claims 1, 3, and 4 of the ’230 patent and claims 1–4 and 6 of the ’607 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Segway Inc., 14 Technology Drive, Bedford, NH 03110
DEKA Products Limited Partnership, 340 Commercial Street, Suite 401, Manchester, NH 03101
Ninebot (Tianjin) Technology Co., Ltd., Building 9, Jiasuqi, Tianrui Road, Science and Technology Park Center, Auto Industrial Park, Wuqing, Tianjin, China

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Powerboard LLC, 9363 E Bahia Drive, Scottsdale, AZ 85260
Metem Teknoloji Sistemleri San, Necatibey Cad. No: 61, Karaköy, Istanbul, Turkey
Changzhou Airwheel Technology Co., Ltd., Fl. 9 Zhongchuang Building, No. 396 Tongjiang Road, Xinbei District, Changzhou, Jiangsu, China
Airwheel, Kabelweg 43 1014 BA, Amsterdam, Netherlands
Nanjing Fastwheel Intelligent Technology Co., Ltd., C2–1 Hongfeng Science & Technology Park, Qixia District, Nanjing, China
Shenzhen Chenduoxing Electronic, Technology Ltd., China, a.k.a. C-Star, 4F, block C11, Fuyuan Industrial Area, Jiuwei, Xixiang, Bao'an, Shenzhen, China
Hangzhou Chic Intelligent Technology Co., Ltd., 2/F, No. 2 Building, Liangzhu University, Science and Technology Park, No. 1 Jingyi Road, Hangzhou, 311112, China
Hovershop, 330 East Orange Thorpe Avenue, Suite K, Placentia, CA 92871
Shenzhen Jomo Technology Co., Ltd., a.k.a. Koowheel, Floor 4th and 7th, Caiyue Building, Meilong Road, Bao'an District, Shenzhen City, 518112, China
Guanghzou Kebye Electronic Technology Co., Ltd., a.k.a. Gotway, A2, 2nd Floor, Building 39, Dayangtian Industry Park, Wanfeng, No. 56, Fengtang Road, Bao'an District, Shenzhen, China
Inventist, Inc., 4901 NW Camas Meadows Drive, Camas, WA 98607

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Honorable David P. Shaw is designated as the presiding Administrative Law Judge.

The Commission has determined to assign this investigation to Judge Shaw, who is the presiding administrative law judge in *Certain Personal Transporters, Components Thereof, and Packaging and Manuals Therefor,* Inv. No. 337–TA–1007, and hereby directs Judge Shaw to consolidate the two proceedings in view of the overlapping general exclusion orders requested in the two investigations.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: September 15, 2016.

Lisa R. Barton,
Secretary to the Commission.

[FR Doc. 2016–22758 Filed 9–20–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Charles Szyman, D.O.; Decision and Order

On February 10, 2016, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Charles Szyman, D.O. (hereinafter, Respondent), of Manitowoc, Wisconsin. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration AS3236406, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, on the ground that he does not have authority to handle controlled substances in Wisconsin, the State in which he is registered with the Agency. Order to Show Cause, at 1 (citing 21 U.S.C. 823(f) and 824(a)(3)).

The Show Cause Order alleged that Respondent is registered as a DATA-waived/100 practitioner pursuant to Certificate of Registration No. AS3236406, with authority to handle controlled substances in schedules II through V, at the registered address of P.O. Box 1450, 3200 Western Avenue, Manitowoc, Wisconsin. *Id.* The Order also alleged that Respondent's registration does not expire until February 28, 2017. *Id.*

The Show Cause Order then alleged that State of Wisconsin Medical Examining Board (hereinafter, Board) issued an order suspending Respondent's authority to practice medicine and surgery, effective October 21, 2015. *Id.* The Show Cause Order thus asserted that "DEA must revoke [Respondent's registration] based upon [his] lack of authority to handle controlled substances in the State of Wisconsin." *Id.* (citing 21 U.S.C. 802(21), 823(f) and 824(a)(3)). The Show Cause Order also notified Respondent of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedure for electing either option, and the consequence of failing to electing either option. *Id.* at 2 (citing 21 CFR 1301.43).

On March 7, 2016, Respondent, through his counsel, requested a hearing on the allegations of the Show Cause Order. Resp.'s Hrng. Req., at 1. In his hearing request, Respondent conceded that his state license had been summarily suspended, but argued that 21 U.S.C. 824(a)(3) does not require that DEA revoke a registration if the practitioner has had his state license suspended. *Id.* at 2. He also requested a stay of the proceeding until after the resolution of the Board's case. *Id.*

The matter was placed on the docket of the Office of Administrative Law Judges, and assigned to the Chief Administrative Law Judge (hereinafter, CALJ). Order Directing the Filing of Government Evidence of Lack of State Authority Allegation and Briefing Schedule, at 1. The same day, the CALJ issued an order directing the Government to "provide its position regarding the Respondent's request for a stay" and to file evidence to support its allegation of Respondent's lack of state authority. *Id.* at 1–2. He also ordered Respondent to file a timely reply if the Government filed a motion for summary disposition. *Id.* at 2.

On March 18, 2016, the Government filed it Motion for Summary Disposition, which it supported by attaching a copy of the Board's October 21, 2015 Order of Summary Suspension. Mot. for Summ. Disp., at Appendix B. Therein, the Government argued that it was undisputed that the Board suspended Respondent's state license on October 21, 2015. Mot. for Summ. Disp., at 2. The Government further argued that because Respondent no longer meets the statutory definition of a practitioner and "the Agency has consistently held that 'the CSA requires the revocation of a registration issued to a practitioner . . . even where a state board has suspended . . . a practitioner's authority with the possibility that the authority may be restored at some point in the future,' " it was entitled to summary disposition and the recommendation that Respondent's registration be revoked. *Id.* at 4 (citations omitted). The Government also requested that the CALJ deny Respondent's stay request. *Id.*

In his Reply, Respondent argued that "the plain language of section 824(a)(3) provides that the loss of state authority constitutes a discretionary, not mandatory, basis for revocation." Respondent Reply to Gov. Mot. for Summ. Disp., at 1 (citing *James Alvin Chaney,* 80 FR 57391 n.1 (2015)).[1] Respondent's Reply, at 1. However, Respondent also acknowledged that the CALJ's recommended decision in *Chaney* "deferred to Agency precedent" and recommended revocation, and thus he would not "belabor his objection." *Id.* Respondent argued, however, that "[a] stay . . . would afford [him] with his due process right to be heard in a meaningful manner in the State . . . proceeding." *Id.* (citing *Dusenberry* v. *United States,* 543 U.S. 161 (2002); *Mathews* v. *Eldridge,* 424 U.S. 319 (1976)).

On March 29, 2016, the CALJ granted the Government's Motion for Summary Disposition, finding that Respondent conceded in his Hearing Request that he is currently without state authority to handle controlled substances in Wisconsin, and thus "no genuine dispute exists over the fact that [Respondent] lacks state authority to handle controlled substances in Wisconsin." Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, at 7. The CALJ also denied Respondent's request for a stay, noting that "the Agency has previously stated that a stay is "unlikely to ever be justified due to ancillary proceedings" and "it is not DEA's policy to stay [administrative] proceedings . . . while registrants litigate in other forums." *Id.* (citing *Grider Drug #1 & Grider Drug #2,* 77 FR 44070, 44104 n.97 (2012); *Newcare Home Health Services,* 72 FR 42126 (2007)).

Neither party filed Exceptions to the CALJ's Recommended Decision. Thereafter, the record was forward to this office for Final Agency Action. Having considered the entire record, I will adopt the ALJ's ruling that a stay of the proceeding was not warranted, his finding that "Respondent lacks state authority to handle controlled substances" and "is not entitled to maintain his DEA registration," and his recommendation that I revoke Respondent's registration. I make the following factual findings.

Findings

Respondent holds DEA Certificate of Registration AS3236406. Pursuant to this registration, Respondent is authorized to dispense controlled substances in schedules II through V, at the registered location of P.O. Box 1450, 2300 Western Avenue, Manitowoc, Wisconsin. Appendix A to Gov. Mot. for Summ. Disp., at 1. Under this registration, Respondent is also authorized to treat up to 100 patients as a DATA-waived physician. *Id.* Respondent's registration does not expire until February 28, 2017. *Id.*

It is undisputed that the Wisconsin Medical Board issued an Order summarily suspending Respondent's state license to practice medicine effective on October 21, 2015. *See also* Appendix B to Gov. Mot. for Summ. Disp., at 3. While according to Respondent's Hearing Request, a hearing to challenge the Board's action was set for May 18, 2016, Respondent's state license remains suspended as of the date of this Decision and Order.[2] Resp. Hrng. Req., at 2. *See also https://app.wi.gov/LicenseSearch/IndividualLicense/SearchResultsSummary* (visited Sept. 13, 2016).

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823, "upon a finding that the Registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." Moreover, DEA has held repeatedly that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012).

This rule derives from the text of two provisions of the CSA. First, Congress defined "the term 'practitioner' [to] mean[ ] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that "[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f). Because Congress has clearly mandated that a physician possess state authority in order to be deemed a practitioner under the Act,

---

[1] Respondent's citation refers to Footnote 1 of the Recommended Decision in *Chaney* and not to the Agency's Decision and Order. In the latter, the Agency made clear that although the language of section 824(a) authorizes either the suspension or revocation of a registration upon the making of one of the five findings enumerated therein, based on the CSA's definition of the term practitioner, *see* 21 U.S.C. 802(21), and the provision which sets forth the criteria for evaluating an application for a practitioner's registration, *see id.* § 823(f), the Agency has consistently interpreted the CSA as mandating the revocation of a practitioner's registration where the practitioner's state authority has been suspended or revoked. 80 FR 57392 n.2. This interpretation has been upheld by the federal courts. As the Fourth Circuit has held, "[b]ecause sections 823(f) and 802(21) make clear that a practitioner's registration is dependent upon the practitioner having state authority to dispense controlled substances, the [Administrator's] decision to construe section 824(a)(3) as mandating revocation upon suspension of a state license is not an unreasonable interpretation of the CSA." *Hooper* v. *Holder,* 481 Fed.Appx. 826, 828 (4th Cir. 2012).

[2] In its Order, the Board found that Respondent "prescribes unusually large amounts of controlled substances, opioid pain medications in particular, without adequate or any medical support" and "without adequate or any physical examinations or medical testing," that he "allowed patients to request specific drugs and dosages," and that he "knows or should know the prescriptions he writes are being diverted, abused and are causing the accidental and intentional deaths of patients and others in the community where he practices." Appendix B (Board Order), at 1–2. The Board concluded that "there is probable cause to believe that unprofessional conduct has occurred" and that "it is necessary to suspend the license and registration of Respondent . . . immediately to protect the public health, safety or welfare." *Id.* at 2 (citing Wis. Admin. Code § Med. 10.02(2)(h) (Nov. 2002) and Wis. Admin. Code §§ Med. 10.03(2)(b) and (c) (Oct. 2013)).

DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices medicine. *See, e. g., Calvin Ramsey,* 76 FR 20034, 20036 (2011); *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci,* 58 FR 51104, 51105 (1993); *Bobby Watts,* 53 FR 11919, 11920 (1988); *see also Hooper* v. *Holder,* 481 Fed. Appx. at 828.

In his Reply to the Government's Motion, Respondent argues that "the plain language of section 824(a)(3) provides that the loss of state authority constitutes a discretionary, not mandatory, basis for revocation." Resp. Reply, at 1. This Agency has explained, however, that Section 824(a)'s grant of authority to suspend or revoke a registration applies across all categories of registration, including manufacturers, distributors, importers, exporters, narcotic treatment programs, list I distributors, and practitioners, and it applies to five different grounds for sanctioning a registrant. *Hooper,* 76 FR, at 71372. The Agency has further explained that "this general grant of authority in imposing a sanction must be reconciled with the CSA's specific provisions which mandate that a practitioner hold authority under state law in order to obtain and maintain a DEA registration." [3] *Id. See also Gozlon-Peretz* v. *United States,* 498 U.S. 395, 407 (1991) ("A specific provision controls over one of more general application."); *Bloate* v. *United States,* 559 U.S. 196, 207 (2010) ("language of a statutory provision, although broad enough to include it, will not be held to apply to a matter specifically dealt with in another part of the same enactment.'").

Thus, in *Hooper* v. *Holder,* a physician whose state authority was suspended for a period of one year, challenged the revocation of his registration, arguing that the Agency "failed to recognize the discretion under § 824(a) to revoke or suspend a registration and that it was impermissible for the [Agency] to conclude that the CSA requires revocation of a practitioner's DEA registration when the practitioner's State license is suspended." 481 Fed. App'x, at 826. The Fourth Circuit rejected the physician's challenge, explaining:

> We find Hooper's contention unconvincing. Section 824(a) does state that the [Agency] may "suspend or revoke" a registration, but the statute provides for this sanction in five different circumstances, only one of which is loss of a State license. Because § 823(f) and § 802(21) make clear that a practitioner's registration is dependent upon the practitioner having state authority to dispense controlled substances, the [Agency's] decision to construe § 824(a)(3) as mandating revocation upon suspension of a state license is not an unreasonable interpretation of the CSA. The [Agency's] decision does not "read[] the suspension option" out of the statute, because that option may still be available for the other circumstances enumerated in § 824(a).

Id. See also Maynard v. *DEA,* 117 Fed. Appx. 941, 945 (5th Cir. 2004) (upholding revocation of DEA registration after Texas DPS summarily suspended practitioner's controlled substance registration, noting that the Agency "has construed the CSA to require revocation when a registrant no longer possesses valid state authority to handle controlled substances"; "We agree with [the] argument that it may have been arbitrary and capricious had the DEA failed to revoke [the physician's] registration under the circumstances.").

Indeed, DEA has interpreted the CSA in this manner for nearly 40 years. *See Frederick Marsh Blanton, M.D.,* 43 FR 27616 (1978). In *Blanton,* a physician's state license was suspended for a period of one year. *Id.* at 27616. The Agency nonetheless revoked the physician's registration, explaining that "it is the Administrator's finding and conclusion that there is a lawful or statutory basis for the revocation of the Respondent's DEA registration. *State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.* The Respondent's registration must, therefore, be revoked." *Id.* at 27617 (emphasis added). *See also Alfred Tennyson Smurthwaite,* 43 FR at 11873 (same).

Put another way, because a practitioner's registration is dependent upon state authority to dispense controlled substances, when that practitioner's state authority has been revoked or suspended, the practitioner no longer meets the statutory definition. *See* 21 U.S.C. § 802(21). And because the CSA makes clear that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for both obtaining and maintaining a practitioner's registration, "revocation is warranted even where a practitioner's state authority has been summarily suspended and the State has yet to provide the practitioner with a hearing to challenge the State's action at which he may ultimately prevail." *Kamal Tiwari,* 76 FR 71604, 71606 (2011); *see also Bourne Pharmacy, Inc.,* 72 FR 18273, 18274 (2007); *Anne Lazar Thorn,* 62 FR 12847 (1997).

In his Reply to the Motion for Summary Disposition, Respondent also argues that a stay "would afford [him] with his due process right to be heard in a meaningful manner in the State Medical Examining Board proceeding." Reply, at 1. Respondent, however, offers no explanation as to how my adjudication of this matter impacts, in any manner, his right to be heard in the State proceeding. Indeed, in circumstances similar to those of Respondent, this Agency "has repeatedly denied requests to stay the issuance of a final order of revocation . . . [because] under the Controlled Substances Act, 'a practitioner must be currently authorized to handle controlled substances . . . to maintain [his] DEA registration.'" *Gregory F. Saric, M.D.,* 76 FR 16821 (2011) (quoting 21 U.S.C. § 802(21)); *see also Irwin August,* 81 FR 3158 (2016). As the Agency has explained, because "whether Respondent's state license will be re-instated is entirely speculative, *id.,* '[i]t is not DEA's policy to stay proceedings . . . while registrants litigate in other forums.'" *August,* 81 FR at 3159 (quoting *Newcare Home Health Servs.,* 72 FR 42126, 42127 n.2 (2007) (citing *Bourne Pharmacy,* 72 FR 18273 (2007))). I therefore affirm the ALJ's ruling denying Respondent's stay request.

In conclusion, because Respondent is not currently authorized to dispense controlled substances in Wisconsin, the State in which he is registered with the Agency, he is not entitled to maintain his registration. Accordingly, I will adopt the ALJ's recommendation that I revoke Respondent's registration.

---

[3] By contrast, in *Bio-Diagnostic International,* 78 FR 39327 (2013), a case involving a list I chemical distributor which did not possess state authority, the Agency held that granting summary disposition to the Government on this basis was improper because neither the provision setting forth the standards for the registration of list I distributors, nor the definition of a distributor, requires that a distributor possess state authority in order to be registered. While *Bio-Diagnostic* involved an application, in a footnote, the decision explained that while "section 824(a)(3) authorizes revocation where a registrant 'has had [its] State license suspended, revoked, or denied by competent state authority and is no longer authorized by State law to engage in the manufacturing [or] distribution of . . . list I chemicals[,]' [this] does not mean that revocation is warranted in all instances." *Id.* at 39330 n.6. Continuing, the decision explained that "[t]his provision grants the Agency discretionary authority to impose an appropriate sanction; the failure to consider factors such as the egregiousness of the misconduct and mitigating factors in imposing the sanction would render the sanction arbitrary and capricious." *Id.*

Order

Pursuant to the authority vested in me by 21 U.S.C. § 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration AS3236406, issued to Charles Szyman, D.O., be, and it hereby is, revoked. This Order is effective immediately.[4]

Dated: September 13, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–22677 Filed 9–20–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Richard J. Settles, D.O.; Decision and Order

On September 9, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Richard J. Settles, D.O. (hereinafter, Respondent), of Grand Junction, Colorado. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration FS3717975, pursuant to which he is authorized to dispense controlled substances in schedules II through V, as a practitioner, at the registered address of 715 Horizon Drive, Suite 200, Grand Junction, Colorado. GX 2, at 1 (citing 21 U.S.C. 824(a)(1) and (4)). The Show Cause Order also proposed the denial of any pending application to renew or modify Respondent's registration, on the ground that his "continued registration is inconsistent with the public interest." *Id.*

As grounds for the proposed actions, the Government alleged that Respondent had materially falsified his March 4, 2013 application for registration. *Id.* at 2 (21 U.S.C. 824(a)(1)). The Order also alleged that he had issued prescriptions for controlled substances without authority to do so under both Arizona and Federal law. *Id.* at 3 (citing 21 U.S.C. 824(a)(4)).

With respect to the material falsification allegation, the Government alleged that on March 4, 2013, Respondent applied for a DEA registration at a location in Chattanooga, Tennessee. *Id.* at 1. The Government alleged that Respondent provided a "yes" answer to the application question: "Has the applicant ever surrendered (for cause) or had a state professional license or controlled substances registration revoked, suspended, restricted, or placed on probation, or is any such action pending?" and that "[i]n furtherance of [his] answer," Respondent explained that on July 17, 2012, "the Arizona Board of Osteopathic Examiners placed my license on a 5 year probation," and that as a result, "I voluntarily surrendered my Arizona license and DEA registration as I knew I was moving to Tennessee in the next few months." *Id.* at 1–2.

The Government then alleged that Respondent's answer was materially false because he was "aware of at least two . . . other state professional license actions" when he submitted the application and failed to disclose them. *Id.* at 2. The Government alleged that these actions included a November 17, 2012 Interim Consent Order issued by the Arizona Board, which restricted Respondent's license to practice osteopathic medicine pending the Board's investigation into whether he violated its July 17, 2012 Order by prescribing controlled substances as his authority to do so had been restricted by that Order. *Id.* As for the second Board action, the Government alleged that on February 6, 2013, Respondent entered into a Stipulation and Order with the Utah Division of Occupational and Professional Licensing, in which he admitted that he had falsified a May 4, 2012 application for licensure in that State, because he failed to disclose that he was then under investigation by the Arizona Board, and that he had surrendered his Utah license to practice as an osteopath. *Id.* at 2–3 (citing 21 U.S.C. 824(a)(1), 823(f), 843(a)(4)(A)).

As for the prescribing allegations, the Government alleged that pursuant to the July 17, 2012 Arizona Board Order, Respondent was restricted from prescribing schedule I through IV controlled substances. *Id.* at 3. The Order alleged that the Board subsequently found that after the effective date of the Order, Respondent became the medical director of a hospice program and prescribed controlled substances to 10 of the program's patients. *Id.* The Order then alleged that "[p]rescribing controlled substances without appropriate authority is contrary to Federal law." *Id.* at 3 (citations omitted).

Next, the Order alleged that on May 7, 2014, one day before the Tennessee State Board of Osteopathic Examination issued a Consent Order which indefinitely suspended his Tennessee license, Respondent applied to modify his registered address from Tennessee to an address in Dolores, Colorado. *Id.* at 4. The Order alleged that Respondent made several additional requests to modify his registered address, concluding with his February 18, 2015 request to change his address to a location in Grand Junction, Colorado and that the Agency approved this request on March 17, 2015. *Id.*

The Order then alleged that prior to the Agency's approval of his modification request, Respondent issued controlled substance prescriptions in Colorado, "in violation of 21 U.S.C. 810(10),[1] 822(e), and 841(a)(1)." *Id.* at 4 (citing, *inter alia,* 21 CFR 1301.12(a), 1301.13(a)). Specifically, the Order alleged that "from July 2014 through February 2015, [Respondent] issued over 250 prescriptions when [he] lacked the requisite federal authority to issue prescriptions in Colorado." *Id.* The Order then set forth multiple instances of such prescriptions. *Id.* at 5–6. The Order further alleged that Respondent "issued multiple prescriptions to patients within a thirty-day window, amounting to prescriptions for large dosages of highly abused controlled substances" and set forth a dozen patients to whom he issued the prescriptions. *Id.* at 6–7.

On September 14, 2015, the Show Cause Order, which also notified Respondent of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence for failing to elect either option, was served on Respondent by certified mail, return receipt requested. GX 4, at 1. Thereafter, on October 14, 2015, Respondent, through his attorney, filed a document entitled "Waiver of Hearing, Statement of Position on the Facts and Law" (hereinafter "Position Statement") with the Office of Administrative Law Judges. *See* 21 CFR 1301.43(c); GX 5. Therein, Respondent acknowledged service of the Order to Show Cause on September 14, 2015, *see* GX 5 at 5, and explained he was waiving his right to a hearing and filing his "Statement of Position on the Facts and Law regarding the matters alleged in the Order to Show Cause." GX 5, at 2.

On February 29, 2016, the Government forwarded its Request for Final Agency action, the Investigative Record, and Respondent's Position Statement. Subsequently, on March 21, 2016, the Government filed an Addendum to its Request for Final Agency Action (hereinafter, First

---

[4] For the same reasons which led the Wisconsin Board to summarily suspend Respondent's osteopathic license, *see supra* note 2, I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

[1] There is no such provision in the CSA.

Addendum). Therein, the Government notified my Office that Respondent did not file his renewal application until February 2, 2106,[2] which was less than 45 days before the expiration date of his registration (Feb. 29, 2016). Noting that under an agency regulation, '"a registrant, who has been served with an Order to Show Cause, [must] file his renewal application at least 45 days before the expiration of his registration, in order for it to continue in effect past its expiration date and pending the issuance of a final order,'" and that Respondent had filed his renewal application less than 45 days prior to the expiration of his registration, the Government argued that Respondent's registration had expired and thus, "the issue to be considered . . . is whether DEA should grant [his] application . . . not whether DEA should revoke Respondent's registration." *Id.* at 1 (quoting *Paul Weir Battershell,* 76 FR 44359, 44361 (2011) (quoting 21 CFR 1301.36(i))).

On April 28, 2016 the Government filed a second Addendum to its Request for Final Agency Action (hereinafter, Second Addendum). Therein, the Government advised that "the Medical Board of Colorado issued an Order of Suspension which suspended Applicant's Colorado medical license, effective Friday, April 22, 2016"; the Government provided a copy of the Board's Order.[3] *Id.* at 1; *see also* Attachment (GX 27), at 1–2. The Board's Order has been made a part of the Investigative Record in this proceeding.

Respondent's Position Statement

Respondent's Position Statement raises various contentions which warrant discussion prior to my determination of the material facts in this matter. As a preliminary matter, Respondent asserts that "in waiving his right to participate in the hearing[,] [he] did not and does not waive any rights other than his right to a hearing" and that "there is no authority in the regulations of the Agency to waive any other rights pertaining to the adjudication of this matter." GX 5, at 1.

Among other things, Respondent contends that the Administrative Law Judge is required, "upon receipt of a waiver of hearing and statement on the matters of fact and law to determine if the statement is admissible, and if so make the statement part of the record." *Id.* at 3 (citing 21 CFR 1316.49). Respondent then argues that he "is entitled to have the ALJ certify the record in this proceeding to the Administrator," that "the ALJ's jurisdiction . . . does not terminate until after he certifies the record," that "a termination of the proceedings that permits the Government's counsel to determine what constitutes the record is a clear violation of this regulation," and that "[t]he ALJ's role and authority is not altered by the waiver of a hearing." *Id.* at 4 (citing 21 CFR 1316.52).

Respondent is mistaken. Under the Agency's rules, absent the filing of a request for a hearing on an Order to Show Cause, the Office of Administrative Law Judges does not acquire jurisdiction over the matter. Here, Respondent did not file a request for a hearing, and indeed, explicitly waived his right to a hearing. Accordingly, no Administrative Law Judge was designated as a presiding officer and because no hearing was held, there was no record to be certified by a member of the Office of Administrative Law Judges.

Thus, the Government, while it was required to submit Respondent's Position Statement with its filing, was otherwise entitled to determine what evidence it would submit to my Office in support of its Request for Final Agency action. Moreover, the Government has represented to me that it provided to Respondent a copy of its Request for Final Agency Action, the Exhibits, the Addendums, and the Attachment to the Second Addendum. Accordingly, as the Government has provided Respondent with all of its filings, Respondent cannot claim that it has been stripped "of its status as a party to the proceeding."[4] *Id.* For the same reason, I reject Respondent's assertion that a "quagmire . . . would ensue if the proceedings were cancelled in their entirety[5] and Government Counsel were permitted to seek a final order by presenting DEA's case directly to the Administrator in *ex parte* communications." *Id.* at 5.

Respondent further argues that under 21 CFR 1301.43(c), I "may not terminate the proceeding and issue [my] final order unless 'all persons entitled to a hearing *or to participate in a hearing* waive . . . their opportunity for the hearing *or to participate in the hearing.*" *Id.* (quoting 21 CFR 1301.43(e))[6] (emphasis in Respondent's Position Statement). Respondent then argues that "DEA is entitled to participate in the hearing and . . . has counsel of record representing it," but "has not waived its opportunity to participate in the hearing." *Id.* at 4. Respondent thus contends that "canceling the hearing and allowing the Administrator to issue [his] final order is not authorized." *Id.*

Once again, Respondent is mistaken. Notwithstanding that an agency regulation applicable to hearings (21 CFR 1316.42(e)) defines the "[t]he term *person* [to] include[] an individual, corporation, government or governmental subdivision or agency," when the Government initiates an Order to Show Cause proceeding, it is not a "person entitled to a hearing" within the meaning of 21 CFR 1301.43.[7] Indeed, this language is fairly read as encompassing only the recipient of the Show Cause Order.

For the same reason, *i.e.,* because it initiated the proceeding, when the Government initiates an Order to Show Cause proceeding, it is not a "person entitled to participate in a hearing pursuant to § 1301.34 or § 1301.35(b)." 21 CFR 1301.43(b). With respect to § 1301.34, this provision applies to only a narrow category of cases which are not initiated by the Government—specifically, where an applicant seeks registration to import schedule I or II controlled substances. Under this provision, the Agency is required to give notice to registered manufacturers as well as other applicants for registration to manufacturer the same basic substance, and upon request of such manufacturer or applicant, the Agency "shall hold a hearing on the application." 21 CFR 1301.34(a). While Government does not initiate the proceeding, it may intervene in the proceeding as a "person entitled to participate in a hearing." 21 CFR 1301.43(b). *See also e.g., Chattem Chemicals, Inc.*, 71 FR 9834, 9834 (2006), *pet. for rev. denied sub nom. Penick Corp, Inc.*, v. *DEA*, 491 F.3d 483, 493 (D.C. Cir. 2007); *Penick Corp., Inc.*, 68 FR 6947, 6947 (2003), *pet. for rev. denied sub nom. Noramco, Inc.*, v. *DEA*, 375 F.3d 1148, 1159 (D.C. Cir. 2004). Indeed, this is the only circumstance in which the Government can be fairly described as a "person entitled to participate in a hearing."[8]

---

[2] On the date the Show Cause Order was issued, Respondent was registered as a practitioner to handle controlled substances in schedules II–V under DEA Registration FS3717975 at the registered address of La Junta Clinic, 715 Horizon Drive, Suite 200, Grand Junction, Colorado; this registration, which was issued on March 5, 2013, was due to expire by its terms on February 29, 2016. GX 1.

[3] The Government certified that a copy of both Addendums was served on Respondent's counsel. First Addendum, at 3; Second Addendum at 2.

[4] As support for this contention, Respondent quotes 20 CFR 404.929, a regulation applicable to certain hearings conducted by ALJs on behalf of the Social Security Administration. *See* GX 5, at 4. This provision has no relevance to this proceeding.

[5] Respondent offers no explanation as to what further rights he believes he is entitled to, given that he has waived his right to a hearing and has filed his Position Statement. Nor does he explain what he believes remains of the proceeding other than the Government's submission of its Request for Final Agency Action and its evidence and my issuance of this Decision and Order.

[6] The correct regulation is 21 CFR 1301.43(e).

[7] Words take their meaning from the context in which they are used, and in this regard the language of 21 CFR 1301.43(a) is probative. It states: "Any person entitled to a hearing pursuant to § 1301.32 or §§ 1301.34–1301.36 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause . . . file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter." The reference provisions apply to applicants for registration whose applications the Agency is proposing to deny, and the holders of registrations whose registrations the Agency is proposing to revoke. As the provision applicable to Respondent states: "[b]efore revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to § 1301.37 and, *if requested by the registrant,* shall hold a hearing pursuant to § 1301.41." 21 CFR 1301.36(d) (emphasis added). Here, however, Respondent did not request a hearing but rather chose to submit a position statement in lieu thereof.

Thus, with respect to this proceeding, the Government is neither a "person[] entitled to a hearing or to participate in a hearing," 21 CFR 1301.43(e), and the only person whose waiver matters for the purpose of cancelling the hearing is Respondent. Because Respondent has waived his right to a hearing, I am authorized to issue this "final order . . . without a hearing."[9] *Id.*

Having reviewed the entire record, including Respondent's Statement of Position, I make the following factual findings.

FINDINGS OF FACT

Jurisdictional Facts

Respondent, a doctor of osteopathic medicine, previously held DEA Certificate of Registration FS3717975, pursuant to which he was authorized to dispense controlled substances in schedules II–V, at the address of La Junta Clinic, 1012 Belmont Ave., La Junta, Colorado. GX 1. This registration was issued on March 5, 2013, after Respondent submitted the application which is the subject of the material falsification allegations. On February 2, 2016, Respondent submitted an application to renew this registration. First Addendum, at 1. However, because Respondent had previously been served with the Show Cause Order, in order for his registration to remain valid pending this proceeding, he was required to submit his application at least 45 days before the date on which the registration was due to expire. 21 CFR 1301.36(i). Accordingly, I find that Respondent's registration expired on February 29, 2016. I further find, however, that Respondent's application remains pending in this proceeding.[10]

The Arizona and Utah Investigations of Respondent

On April 29, 2010, the mother of Respondent's patient K.K. made a complaint to the Arizona Board of Osteopathic Examiners alleging that K.K. was a heroin addict and that Respondent was prescribing drugs and quantities that "were inappropriate [given] K.K.'s history with substance abuse." GX 8, at 2. The same day, the Board notified Respondent that it was initiating an investigation. *Id.* at 1.

Thereafter, Respondent was invited to attend an investigative hearing which was conducted on September 24, 2011; the hearing was continued to allow the Board to obtain additional information and conduct "a chart review of thirty (30) patients." *Id.* The Board also ordered Respondent to undergo a psychological evaluation and requested that he provide additional documentation to it. *Id.*

On April 10, 2012, the Board notified Respondent "that the Investigative Hearing would continue on May 19, 2012." *Id.* On that date, the Board conducted the hearing with Respondent present and represented by counsel. *Id.* Thereafter, the Board issued a decision and order which made factual findings and legal conclusions regarding Respondent's prescribing to K.K. as well as its chart review.

With respect to K.K., the Board found that she was Respondent's patient "from March 2005 through March 2010, with a lapse in care from February 2006 to early 2009." *Id.* at 2. The Board found that at K.K.'s second visit, Respondent prescribed Percocet to her in quantities ranging from 120 to 180 dosage units each month as well as 90 Xanax and 30 Ambien each month. *Id.* The Board further found that "Respondent failed to obtain prior medical records or to perform a workup on K.K. and no consultations were ordered." *Id.* It also found that "[t]he majority of K.K.'s medications were obtained through Respondent's office" and that he "did not enter into a medication contract with [her] until May 5, 2010 for Suboxone." *Id.*

Continuing, the Board found that K.K. "returned to Respondent . . . in 2009 and . . . was started on" 90 Percocet and 90 Soma, and that "[i]n October 2009, K.K. overdosed and was taken to the hospital." *Id.* The Board found that "Respondent continued" to provided K.K. with prescriptions each month for 120 dosage units of Percocet, 90 Xanax, and 30 Ambien until March 2010, when he increased her Percocet prescription to 180 du per month. *Id.* According to the Board, K.K. overdosed again on March 17, 2010 as well as on April 11, 2010. *Id.* at 2–3.

With respect to the chart review, the Board found that "Respondent prescribed controlled substances to chronic pain patients" and that "[p]harmacy inquiries and drug screens were ignored in patients that were clearly diverting." *Id.* at 3. The Board further found that "Respondent deviated from the standard of care by failing to":

> (1) "stop prescribing controlled substances for patients that had overdosed";
> (2) "recognize drug seeking behavior in patients";
> (3) "request prior medical records";
> (4) "obtain appropriate laboratory testing";
> (5) "conduct a physical exam in at least one patient";
> (6) "obtain consultations"; and
> (7) "follow the directions of specialist [sic] or recommendations when consultations were obtained."

Id.

The Board thus found that "Respondent practice[d] medicine in a manner that harmed or had potential to harm patients and fell below the community standard . . . and . . . this conduct endangered a patient or the public's health." *Id.* And the Board concluded that Respondent engaged in unprofessional conduct by " '[e]ngaging in the practice of medicine in a manner that harms or may harm a patient or that the board determines falls below the community,' " as well as that he engaged in " '[a]ny conduct or practice that endangers the public's health or may reasonably be expected to do so.'" *Id.* at 4 (quoting Ariz. Rev. Stat. §§ 32–1854(6) & (38)).

---

[8] 21 CFR 1301.43(b) also refers to the provisions of 1301.35(b), which allow for registered bulk manufacturers of a basic substance in schedule I or II (as well as applicants for registration to manufacture the basis substance) to "participate in a hearing" when the Government has issued a Show Cause Order proposing the denial of an application for registration "to manufacture in bulk" the same basic class and the applicant has requested a hearing. Here too, the Government is not a "person entitled to participate in a hearing." Rather, it is initiator of the proceeding.

[9] The Agency's longstanding and consistent practice is that where a party waives its right to a hearing, the Government is entitled to present its evidence directly to the Administrator, who is the ultimate factfinder. *See, e.g., Cf. Reckitt & Colman, Ltd.* v. *Administrator*, 788 F.2d 22, 26 (quoting 5 U.S.C. 557(b) ("On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision . . . .")). This practice has been followed in hundreds of cases over the years.

[10] Respondent previously held DEA Certificate of Registration BS3176105. GX 7, at 3. Pursuant to this registration, Respondent was authorized to dispense controlled substances in schedules II through V, at the registered location of 10752 North 89th Place, Suite 218, Scottsdale, Arizona 85620. GX 9, at 1. However, on July 30, 2012, Respondent surrendered this registration "[i]n view of [his] alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practice on [his] part." *Id.* This registration was retired the following day. GX 7, at 3.

Based on the above, the Board censured Respondent and "restricted" him "from prescribing or recommending Schedule I, II, III or IV controlled substances for a period of two years . . . from" the Order's effective date. The Board also restricted him from practicing pain management, imposed a civil penalty of $1,000 and placed him on probation for a period of five years, the terms of which included that he "obey all federal, state and local laws, and rules governing the practice of medicine in the State of Arizona." *Id.* The Order became effective on July 17, 2012. GX 10, at 3.

As found above, on July 30, 2012, Respondent voluntarily surrendered his then DEA registration (BS3176105). Thereafter, on October 12, 2012, the Board received information form anonymous sources that Respondent "may be prescribing controlled substances." GX 16, at 1. In response, the Board queried the Board of Pharmacy's Controlled Substances Prescription Monitoring Program "for all controlled substances written or ordered by [Respondent] from June 11, 2012 through October 15, 2012." *Id.* The query showed that between July 17, 2012 and October 15, 2012, Respondent had issued 99 prescriptions for schedule II drugs, 23 prescriptions for schedule III drugs, and 70 prescriptions for schedule IV drugs. *Id.* at 1–2. The Board identified one patient Respondent saw at his office who received a prescription for temazepam on August 21, 2012, and 11 patients at hospices in Tuscon and Mesa to whom he either prescribed or ordered the dispensing of controlled substances, which included morphine, hydromorphone, oxycodone, lorazepam and temazepam. *Id.* at 2–6. Moreover, Respondent issued 17 controlled substance prescriptions or orders for the dispensing of controlled substances for 12 patients after he surrendered his DEA registration. *Id.*

On November 9, 2012, Respondent was interviewed by the Board and admitted "that he had signed prescriptions for Schedule I, II, III or IV controlled substances after the Effective Date" of the Order. GX 10, at 4. Respondent denied having "written prescriptions for patients in his private practice" and "stated that he had only written or authorized prescriptions in his capacity as the . . . medical director for various hospice locations."[11] *Id.*

On November 16, 2012, Respondent entered into an Interim Consent Agreement which the Board approved the following day. *Id.* at 2, 5. Respondent admitted to the findings of fact contained therein, including that he had prescribed or ordered controlled substances after the July 17, 2012 Order became effective, as well as the legal conclusion that he had engaged in unprofessional conduct by "[v]iolating a formal order, probation or a stipulation issued by the board." *Id.* at 1, 4. The Board then ordered that Respondent be "restricted from practicing medicine until the investigation" was completed and "he appear[ed] before the Board . . . for resolution" of the matter. *Id.* at 4.

On May 12, 2014, Respondent entered into a Consent Agreement and Order for Voluntary Surrender of Licensee. GX 12, at 1, 5. Therein, Respondent waived his right to a hearing before the Board. *Id.* at 2. The Board found, *inter alia,* that on August 1, 2012, Respondent had "entered into an Independent Contractor Agreement with Hospice Family Care, Inc.[,] to continue to serve as its Executive Medical Director of Hospice" and that he had "signed prescriptions for controlled substances for ten patients "after the effective date of the [July 17, 2012] Board Order." *Id.* at 3.

While the Arizona Board's investigation was ongoing, Respondent was also the subject of disciplinary proceedings brought by the Utah Division of Occupational and Professional Licensing against his licenses to practice osteopathy and prescribe controlled substances in that State. GX 11, at 1. On February 4, 2013, Respondent entered into a Stipulation and Order with the State in which he admitted that on May 4, 2012, he had submitted an application for licensure as an osteopath and represented on the application "that he was not currently under investigation by any licensing agency, even though [he] knew he was currently under investigation in Arizona." *Id.* at 3. Respondent admitted that his conduct constituted both "unprofessional conduct as defined in Utah Code Ann. § 58–1–501(2)(a) and unlawful conduct as defined in Utah Code Ann. § 58–1–501(e)." *Id.* Respondent agreed to surrender his licenses to practice as an osteopath and to administer and prescribe controlled substances and to not reapply for such licenses for a period of five years. *Id.* On February 6, 2013, the Division approved the Order. *Id.* at 6.

Respondent's March 2013 DEA Application, the Tennessee Board Action, and His Subsequent Address Changes

On March 4, 2013, Respondent applied for a new DEA registration at an address in Chattanooga, Tennessee. GX 6, at 2. On the application, Respondent was required to answer four liability questions. With respect to Question Two, which asked, *inter alia,* whether Respondent had ever surrendered (for cause) his DEA registration, Respondent answered "yes." GX 7, at 2. After listing the incident date as "7/17/2012" and the incident location as "Scottsdale, AZ," Respondent explained the nature of the incident as follows: "AN ADDICTION PATIENT OF MINE ESCALATED THE USE OF HER MEDICATIONS AND ENDED UP IN THE ER. SHE WAS DISCHARGED FROM THE ER UNHARMED BUT HER MOTHER COMPLAINED TO THE ARIZONA OSTEOPATHIC BOARD OF EXAMINERS. THEY PLACED MY LICENSE ON SUSPENSION." *Id.* As for the "incident result," Respondent explained: "I VOLUNTARILY SURRENDERED MY ARIZONA MEDICAL LICENSE AND DEA REGISTRATION AS I NEW [sic] THAT I WAS MOVING TO TENNESSEE IN THE NEAR FUTURE." *Id.*

As for Question Three, it asked: "Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?" *Id.* Respondent again answered "Yes" and listed the same incident date and location as he did in his previous answer. *Id.* As for the nature of the incident, Respondent explained: "THE ARIZONA BOARD . . . PLACED MY LICENSE ON A 5 YEAR PROBATION." *Id.* He then explained the incident result as: "I VOLUNTARILY SURRENDERED MY ARIZONA LICENSE AND DEA REGISTRATION AS I KNEW I WAS MOVING TO TENNESE IN THE NEXT FEW MONTHS." *Id.* at 3.

Respondent did not disclose on the application the November 16, 2012 Interim Consent Agreement with the Arizona Board. *See id.* He also did not disclose the February 6, 2013 Stipulation and Order with the State of Utah. *Id.*

As found above, the next day, Respondent was issued a new registration which authorized him to dispense controlled substances in schedules II through V, at a location in

---

[11] Under the probationary terms of the July 17, 2012 Order, Respondent was required to hire a practice monitor. GX 10, at 4. During the November 9 interview, "Respondent stated that he did not hire a practice monitor because he was not actively practicing in Arizona." *Id.*

Chattanooga, Tennessee; this registration did not expire until February 29, 2016. Shortly thereafter, Respondent sought to change his registered address to a location in Hixson, Tennessee, which the Agency approved on April 3, 2013. GX 6, at 5.

However, on March 17, 2014, Respondent entered into a Consent Order with the Tennessee Board of Osteopathic Examination. GX 13, at 7. The Order was based on the July 17, 2012 and November 17, 2012 Arizona Orders, as well as the Utah Stipulation and Order. GX 13, at 3–4. Respondent agreed that the "disciplinary actions in Utah and Arizona . . . constitute [sic] unprofessional conduct" in that they involved "[u]nprofessional, dishonorable or unethical conduct" which, while it occurred in other States, was also grounds for discipline in Tennessee. *Id.* (citing Tenn. Code Ann. §§ 63–9–111(b)(1) & (b)(21)). Respondent further agreed to the indefinite suspension of his Tennessee license. *Id.* at 4. On May 7, 2014, the Board approved the Order. *Id.* at 6.

According to Respondent, in July 2014, he moved to Grand Junction, Colorado, where he was also licensed, and began working for Dr. Rebecca Tolby, and worked for her for 11 months. GX 5, at 11 (Resp. Position Statement). On some date which is not clear on the record,[12] Respondent sought to modify his registered location to an address in Colorado; however, the modification was not approved until April 6, 2015. GX 6, at 6 (Diversion Investigator's (DI) Declaration); *see also* GX 7, at 1 (Certification of Registration History).

In her Declaration, the DI stated that on December 1, 2014, she phoned "Respondent regarding his lack of authority to write prescriptions in the State of Colorado" and offered him "the opportunity to surrender [his] DEA registration." GX 6, at 6. According to the DI, "[t]hat same evening . . . Respondent attempted to modify his registered address again from Tennessee to New Mexico."[13] *Id.* However, Respondent subsequently changed his modification request "back to Colorado."[14] *Id.*

The DI's Investigation of Respondent's Controlled Substance Prescribing in Colorado

On April 30, 2015, the DI served a Notice of Inspection on five pharmacies located in Grand Junction, Colorado seeking to obtain copies of the prescriptions written by Respondent and dispensing reports showing the prescriptions he had written "from approximately July 2014 through February 2015." GX 6, at 7–8. Upon reviewing the records, the DI prepared a list by month of 89 controlled substance prescriptions (some of which provided for refills) Respondent issued from July 29, 2014 through December 1, 2014 while practicing in Grand Junction, Colorado, *id.* at 7–10; copies of the prescriptions were submitted for the record.[15] *See* GXs 14, 15, 20, 21, 22, 23, 24, 25. Moreover, the dispensing reports obtained from two of the pharmacies showed that Respondent issued additional controlled substance prescriptions even after December 1, 2014, the date on which he was told by the DI that he was not authorized to issue such prescriptions in Colorado. *See* GX 22, at 7 (report obtained from Palisade Pharmacy of Palisade, Colorado showing prescriptions for Tramadol issued to M.B. on Dec. 18, 2014 (filled on Dec. 29, 2014) and on January 26, 2015 (filled that day)); GX 25, at 7 (report obtained from Walgreens of Clifton, Colorado showing prescription for clonazepam issued to A.O. on Mar. 2, 2015 and dispensed by pharmacy on Mar. 3, 2015).

The Colorado Board Proceeding

On April 22, 2016, the Colorado Medical Board suspended Respondent's license to practice medicine pending proceedings for suspension or revocation. The suspension was based on the Board's finding that there is "reasonable grounds to believe that Respondent was guilty of a deliberate and willful violation of the Medical Practice Act" in that he "authorized prescriptions for controlled substances for at least four patients . . . using another physician's DEA registration" when he did not have an active DEA registration number. April 2016 Addendum to Government's RFAA, GX 27. As of the date of this Decision and Order, Respondent's Colorado license remains suspended. *See https://www.colorado.gov/dora/licensing/Lookup/Licensedlookup.aspx* (visited September 13, 2016).

Respondent's Position Statement

In support of his Position Statement, Respondent provided an affidavit. Therein, Respondent states that he "take[s] full responsibility for my actions that resulted in the probation and ultimate surrender of my Arizona license" and that he since "learned a great deal on the proper prescribing of controlled substances." GX 5, at 11. He further asserts that "I did not fully understand the scope of my initial restriction, which caused me to inadvertently violate that restriction." *Id.*

Respondent further asserts that "[s]ince 2012, [he] ha[s] taken a number of steps to ensure that my prescribing practices are compliant with federal and state law" and that in "the past year," he has "been a member of the Colorado Consortium for Prescription Drug Abuse Prevention" and that "[t]he program is helpful to keep abreast of the latest trends on opioid abuse and strategies for prevention." *Id.* at 11–12. He further states that in 2014, he attended lectures during a medical convention on the "Tennessee Substance Abuse Epidemic" and "Office Based Opioid Withdrawal." *Id.* at 12.

In his affidavit, Respondent states that "I have had some challenges with my state medical licenses, all of which arise from the suspension of my Arizona license." *Id.* He then maintains that "I have tried to be as transparent as possible in communicating these issues to the various state medical boards and the local DEA offices that have conducted pre-registration investigations." *Id.* at 13.

---

[12] In an affidavit attached to his Position Statement, Respondent asserted that "[w]hen I moved to Colorado in 2014, I applied to modify my DEA registration to my Colorado address." GX 5, at 13. Respondent did not, however, specify the date on which he applied for the modification. *Id.*

[13] Respondent also obtained an osteopathic medicine license in New Mexico in May 2012; he provided the Agency with a contact address in Albuquerque from December 2014 through February 2015, but there is no indication in the record that he practiced in New Mexico. Respondent admits that the New Mexico Board of Osteopathic Medical Examiners (NMBOME) had opened an investigation into his license but that his license had been renewed on August 19, 2015. GX 5 at 12. However, the NMBOME Web site states that Respondent's Pharmacy license expired on March 1, 2016, and that his osteopathic license expired on July 1, 2016. *See http://verification.rld.state.nm.us/Details.aspx?agency_id=l&license_id=625477.*

[14] On September 14, 2015 (the same date the Show Cause Order was served), Respondent's registered address was changed to the La Junta Clinic, 1012 Belmont Avenue, in La Junta, Colorado. GX 7, at 1.

[15] As discussed above, the Government also alleged that Respondent "issued multiple prescriptions to patients within a thirty-day window, amounting to prescriptions for large dosages of highly-abused controlled substances." GX 2, at 6. As support for the allegation, the DI listed 11 patients who received additional prescriptions within 30 days of having received prescriptions from Respondent. GX 6, at 10–11. While Respondent violated federal law when he issued the prescriptions because he was not registered in Colorado, the Government did not allege that any of these prescriptions lacked a legitimate medical purpose and thus violated 21 CFR 1306.04(a) or a similar provision under Colorado law. Beyond that, in some instances the prescriptions were issued 28 days after the previous prescriptions, which hardly suggests that patients were seeking refills that were too early. While in other instances, the time between the prescriptions was only two or three weeks, the Government did not address why, given the dosing instruction, the refill was too early. I thus reject the allegation.

As for his conduct in issuing controlled substance prescriptions in Colorado when he was not registered in the State, Respondent states that he "was unaware when I moved to Colorado that I was not able to prescribe controlled substances until the DEA actually approved the modification of my . . . registration to my new address." *Id.* Respondent states that he thought that he could prescribe controlled substances in Colorado "so long as I had submitted my request for a modification." *Id.* Respondent then states that he "take[s] full responsibility" for this misconduct which was based on his "misunderstanding of the law and not on any intentional effort to circumvent the" CSA. *Id.* at 14.

According to Respondent, "[a]s soon as I understood my mistake, I immediately stopped prescribing controlled substances." *Id.* However, as found above, the reports of Respondent's dispensings that were provided by the Palisade Pharmacy and Walgreens show that Respondent issued additional prescriptions after the DI told him on December 1, 2014 that he lacked authority to write prescriptions in Colorado.[16] I thus find that Respondent's statement is false.

Respondent further states that he "understand[s] that the allegations in the . . . Order to Show Cause are very serious and that compliance with the DEA's regulations on prescribing controlled substances is crucial to prevent . . . diversion and abuse of controlled substances." *Id.* at 17. Notably, Respondent did not address the allegation that he materially falsified his March 4, 2013 application for a DEA registration. *See generally id.* at 10–17.

DISCUSSION

Pursuant to section 303(f) of the Controlled Substances Act, "[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f). Section 303(f) further provides that an application for a practitioner's registration may be denied upon a determination "that the issuance of such registration . . . would be inconsistent with the public interest." *Id.* In making the public interest determination, the CSA requires the consideration of the following factors:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The Applicant's experience in dispensing . . . controlled substances.
>
> (3) The Applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

Id.

"These factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether . . . an application for registration [should be] denied." *Id.* Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." *MacKay* v. *DEA*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman*, 567 F.3d 215, 222 (6th Cir. 2009) (quoting *Hoxie*, 419 F.3d 477, 482 (6th Cir. 2005))).[17]

Pursuant to section 304(a)(1), the Attorney General is also authorized to suspend or revoke a registration "upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter." 21 U.S.C. § 824(a)(1). It is well established that the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. § 824(a), are also properly considered in deciding whether to grant or deny an application under section 303. *See The Lawsons, Inc.*, 72 FR 74334, 74337 (2007); *Anthony D. Funches*, 64 FR 14267, 14268 (1999); *Alan R. Schankman*, 63 FR 45260 (1998); *Kuen H. Chen*, 58 FR 65401, 65402 (1993).

Thus, the allegation that Respondent materially falsified his application is properly considered in this proceeding. *See Samuel S. Jackson*, 72 FR 23848, 23852 (2007). Moreover, just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(1), it also provides an independent and adequate ground for denying an application. *The Lawsons*, 72 FR at 74338; *cf. Bobby Watts, M.D.*, 58 FR 46995 (1993); *Shannon L. Gallentine*, 76 FR 45864, 45866 (2011).

In this matter, I conclude that there are three independent grounds for denying Respondent's pending application. First, he materially falsified his March 4, 2013 application. Second, by prescribing controlled substances in both Arizona and Colorado when he was not legally authorized to issue such prescriptions in the respective State, he violated the CSA and DEA regulations and thus has committed acts which render his registration "inconsistent with the public interest." 21 U.S.C. § 823(f). Third, as a result of the Colorado Board's suspension of his osteopathic license, he lacks authority under state law to dispense controlled substances in the State in which he now seeks registration. *See id; see also id.* § 802(21).

The Material Falsification Allegation

As found above, the evidence shows that when Respondent submitted his application for a registration on or about March 5, 2013, he answered "Yes" to two liability questions.[18] GX 7, at 2. Question Three asked: "Has the applicant ever surrendered for cause or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?" Respondent checked the "yes" box and provided the following information:

> Incident Date: 07/17/2012. Incident Location: Scottsdale, AZ. Incident Nature: The Arizona Board of Osteopathic Examiners placed my license on a 5 year probation. Incident Result: I voluntarily surrendered my Arizona license and DEA registration as I knew I was moving to Tennessee in the next few months.

Id.

The Government alleges that Respondent's answer was materially false because Respondent failed to disclose the November 2012 Interim Consent Agreement he entered into with the Arizona Board and the February 2013 Stipulation and Order he entered into with the Utah Division of Occupational and Professional Licensing. Request for Final Agency Action, at 11–13. I agree with the Government that Respondent materially falsified his application, but only with respect to his failure to disclose the November 2012 Interim Consent Agreement with Arizona.

---

[16] While Respondent offered an extensive explanation of his practice, at least as it existed prior to the Colorado Board's suspension of his medical license, which involved working in rural Colorado, the Agency has made clear that it does not consider so-called community impact evidence relevant in making the public interest determination in the case of prescribing practitioners. *See Linda Sue Cheek*, 76 FR 66972, 66972–73 (2011); *Gregory Owen*, 74 FR 36751, 36756–57 (2009).

[17] "In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct." *Jayam Krishna-Iyer*, 74 FR 459, 462 (2009).

[18] The second question asked Respondent, *inter alia*, whether he had ever surrendered his DEA registration for cause. The Government does not allege that Respondent materially falsified his application in answering this question.

The Supreme Court has held that "the most common formulation" of the concept of materiality is that "a concealment or misrepresentation is material if it 'has a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed." *Kungys* v. *United States,* 485 U.S. 759, 770 (1988) (quoting *Weinstock* v. *United States,* 231 F.2d 699, 701 (D.C. Cir. 1956) (other citation omitted)) (quoted in *Samuel S. Jackson,* 72 FR 23848, 23852 (2007)); *see also United States* v. *Wells,* 519 U.S. 482, 489 (1997) (quoting *Kungys,* 485 U.S. at 770); *Arthur H. Bell,* 80 FR 50035, 50038 (2015). The Court has further explained that "[i]t has never been the test of materiality that the misrepresentation or concealment would more likely than not have produced an erroneous decision, or even that it would more likely than not have triggered an investigation." *Kungys,* 485 U.S. at 771 (emphasis added). Rather, the test is "whether the misrepresentation or concealment was predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision." *Id.* " '[T]he ultimate finding of materiality turns on an interpretation of substantive law,' " *id.* at 772 (int. quotations and other citation omitted), and must be shown "by evidence that is clear, unequivocal, and convincing." *Id.*

Respondent's failure to disclose the Arizona Interim Consent Agreement clearly meets the standard of materiality. As found above, the Consent Agreement was based on the Board's findings that even after the Board had restricted him from prescribing controlled substances, Respondent continued to dispense controlled substances in that State and did so for nearly three months after the effective date of the Board's Order by either issuing prescriptions or ordering the dispensing of controlled substances. As the evidence shows, Respondent dispensed 99 prescriptions/orders for schedule II drugs, 23 prescriptions for schedule III drugs, and 70 prescriptions for schedule IV drugs after the effective date of the Board's Order and when he no longer held authority under state law and DEA regulations. *See* 21 CFR 1306.03(a) (requiring for a legal prescription that an individual practitioner be "[a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and . . . [e]ither registered or exempted from registration").

Moreover, Respondent issued multiple prescriptions or ordered the dispensing of controlled substances even after he surrendered his DEA registration on July 30, 2012.[19] *See* 21 U.S.C. 843(a)(3) ("It shall be unlawful for any person knowingly or intentionally . . . to use in the course of the . . . dispensing of a controlled substance, a registration number which is fictitious, revoked, suspended, expired, or issued to another person[.]"); *id.* § 822(a)(2) ("Every person who dispenses . . . any controlled substance, shall obtain from the Attorney General a registration . . . ."); *see also* 21 CFR 1306.03(a).

In determining whether the granting of an application is consistent with the public interest, the Agency is required to consider both "[t]he Applicant's experience in dispensing . . . controlled substances" and "compliance with applicable State [and] Federal . . . laws relating to controlled substances." 21 U.S.C. 823(f)(2) & (4). Thus, while Respondent disclosed the July 2012 Arizona Board Order on his application, his failure to disclose the November 2012 Order was clearly "capable of affecting" the Agency decision to grant his application because the Order was based on the additional misconduct he committed with respect to the dispensing of controlled substances when he no longer held authority under the CSA and Arizona law. *Kungys,* 485 U.S. at 771.[20]

As noted above, in his affidavit, Respondent did not address his material falsification of the 2013 application. However, in his Position Statement, he admits (through his counsel) that he "did not provide a complete answer to the liability question," but then contends that "there was never intent . . . to withhold information from DEA, to be untruthful, and/or to omit relevant information to influence DEA's decision." GX 5, at 4–5.

However, the statement made by Respondent's counsel is not evidence, *see INS* v. *Phinpathya,* 464 U.S. 183, 186 n.6 (1984), and I conclude that Respondent submitted his 2013 DEA application with fraudulent intent. As explained above, the November 2012 Order, which was issued only three plus months before he submitted his application, establishes that Respondent had engaged in additional misconduct and disobeyed the Board's earlier Order as well as issued prescriptions after he surrendered his DEA registration. So too, Respondent's failure to disclose the Arizona investigation on his Utah application is probative evidence of his intent or lack of mistake in failing to disclose the November 2012 Arizona order on his DEA application. *See Arthur H. Bell,* 80 FR 50035, 50038 (2015); *cf.* Fed. R. Evid. R. 404(b)(2). Accordingly, I conclude that Respondent materially falsified his March 4, 2013 application for a DEA registration in Tennessee. This conclusion provides reason alone to deny his pending application.

The Public Interest Factors

In its Request for Final Agency Action as initially submitted, the Government argues that Factors Two, Four and Five support the denial of Respondent's application.[21] Govt. Request at 14–17. I

---

[19] While Respondent's loss of his state authority rendered his subsequent issuance of the prescriptions and orders unlawful under the CSA even without his having formally surrendered his DEA registration, Respondent's continued dispensing of controlled substances after he surrendered his registration begs the question of what consequences he believed were attendant to the surrender of his DEA registration. However, in his Position Statement, Respondent does not address the question.

[20] Given this finding, I need not decide whether Respondent's failure to disclose the Utah Stipulation and Order was material to the Agency's determination as to whether to grant his application for registration in Tennessee.

[21] In the Request for Final Agency Action, the Government argued that Factor One—The Recommendation of the Appropriate State Licensing Board—"neither weighs in favor nor weighs against the [denial] of Respondent's" application for registration." Req. for Final Agency Action, at 14.

While Respondent held a Colorado license on the date the Government submitted its Request for Final Agency Action, the Board subsequently suspended his license to practice medicine on the ground that he authorized controlled substance prescriptions "using another physician's DEA registration" after his DEA registration expired. GX 27, at 1. While Respondent apparently has not had a hearing on these allegations, the fact remains that he does not currently possess authority to dispense controlled substances in Colorado, the State in which he is seeking registration.

DEA has long held that the possession of state authority to dispense controlled substances in the State in which a practitioner engages in professional practice is a prerequisite for obtaining a DEA registration in that State. *See Frederick Marsh Blanton,* 43 FR 27616, 27617 (1978) ("State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration."); *see also* 21 U.S.C. § 802(21) (defining "[t]he term 'practitioner' [to] mean[] a physician . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices to . . . dispense . . . a controlled substance in the course of professional practice."); *id.* § 823(f) ("The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices."); *United States* v. *Moore,* 423 U.S. 122, 140–41 (1975) ("In the case of a physician, this scheme contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice."). The Agency has further held that this rule applies even where a practitioner's state authority has been summarily suspended and the State has yet to agree that the evidence with respect to Factor Two and Four establishes a *prima facie* case to deny Respondent's application. And having reviewed Respondent's Position Statement, I hold that he has failed to present sufficient evidence to rebut the conclusion that his "registration would be inconsistent with the public interest." 21 U.S.C. § 823(f).

Factors Two and Four—the Applicant's Experience in Dispensing Controlled Substances and Compliance With State and Federal Laws Related to Controlled Substances

The Government contends that the various Arizona Board Orders establish that Respondent's experience in dispensing controlled substances and his compliance with state and federal laws related to controlled substances support the denial of his application and that the Board's factual findings and legal conclusions are entitled to preclusive effect in this proceeding. Req. for Final Agency Action, at 14–15. I agree in part.

Based on its findings that Respondent deviated from the standard of care in his treatment of K.K. as well as at least 30 patients, to include prescribing excessive controlled substances to chronic pain patients, and that he ignored pharmacy inquiries and drug screenings in patients who were clearly diverting, the Board restricted him from prescribing or recommending controlled substances for two years.[22] *Id.* at 4. Nonetheless, after the effective date of the Order, Respondent continued to issue controlled substance prescriptions as well order the administration of controlled substances to hospice patients. These prescriptions and orders violated the CSA and DEA regulations because he lacked the requisite state authority to dispense controlled substances. 21 CFR 1306.03(a). *See also* Ariz. Rev. Stat. § 32–1854 (25). Moreover, Respondent issued at least 17 of these prescriptions and orders for administration even after he surrendered his registration. 21 U.S.C. 841(a)(1), 843(a)(3), 822(a)(2). Thus, by itself, Respondent's unauthorized dispensing of controlled substances while practicing in Arizona establishes that his registration would be "inconsistent with the public interest." 21 U.S.C. 823(f).

Moreover, there is additional evidence of prescribing violations that supports this conclusion. As found above, upon moving to Colorado, Respondent proceeded to issue numerous controlled substance prescriptions without being registered in that State.

Under DEA's regulation, where a registrant seeks to change his registered location, the registrant must apply to modify his registration, 21 CFR § 1301.51(a), and this regulation clearly states that a "request for modification shall be handled in the same manner as an application for registration." *Id.* § 1301.51(c). Moreover, under 21 CFR 1301.13(a), "[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person." *Id.; see also Anthony E. Wicks,* 78 FR 62676, 62678 (2013). Thus, a registrant may "not engage in any activity for which registration is required until the application . . . is granted and a . . . [r]egistration is issued." 21 CFR 1301.13(a). *See also Mark Koch* 79 FR 18714 (2014).

Here, the evidence shows that between July 29, 2014 and December 1, 2014, Respondent issued 89 prescriptions for controlled substances while practicing in Grand Junction, Colorado, when he did not hold a DEA registration in the State and was therefore not authorized to dispense controlled substances in the State. 21 U.S.C. 822(e) ("A separate registration shall be required at each principal place of business or professional practice where the applicant . . . dispenses controlled substances. . . ."); 21 CFR 1301.12. Moreover, while Respondent claims that he was unaware that he could not issue controlled substance prescriptions until the Agency approved his modification request and that he stopped after he was told by the DI that he could not write prescriptions until his request was approved, the evidence shows that he issued further controlled substance prescriptions after he was told by the DI that he lacked authority to do so in Colorado.

Accordingly, I conclude that Respondent violated the CSA and DEA regulations when he prescribed controlled substances in Colorado before April 6, 2015. These findings, particularly when considered in light of the extent of the Applicant's prescribing violations in Arizona, support the conclusion that granting Applicant's application "would be inconsistent with the public interest." 21 U.S.C. 823(f).[23]

SANCTION

Where, as here, the Government has established grounds to deny an application, Respondent must then "present[ ] sufficient mitigating evidence" to show why he can be entrusted with a new registration. *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988)). " 'Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where [an applicant] has committed acts inconsistent with the public interest, the [applicant] must accept responsibility for [his] actions and demonstrate that [he] will not engage in

---

provide him/her with a hearing to challenge the State's action. *See Bourne Pharmacy,* 72 FR 18273, 18274 (2007).

Because Respondent's Colorado medical license has been suspended, he is no longer currently authorized to dispense controlled substances in Colorado, the State in which he seeks registration. Thus, he no longer meets the CSA's requirement that he be authorized to dispense controlled substances in the State where he is registered. This conclusion provides a further reason to deny his application.

[22] While the Government argues that the Board's findings establish that Respondent "failed to comply with state law by deviating from the standard of care in issuing prescriptions for controlled substances," the Arizona Board did not find that he engaged in "[p]rescribing, dispensing, or administering controlled substances . . . for other than therapeutic purposes." *See* Ariz. Rev. Stat. § 32–1854. In short, neither of the provisions the Board found Respondent to have violated make specific reference to controlled substances but are provisions generally applicable to all osteopathic physicians. As such, while Respondent's conduct involved controlled substances, the provisions he violated are not laws related to controlled substances.

Notwithstanding that the Board did not find that he prescribed "for other than therapeutic purposes," the Board's findings and conclusions might well have supported an adverse finding under Factor Two because "DEA's authority to [deny an application] is not limited to those instances in which a practitioner intentionally diverts," and "[a] practitioner who ignores the warning signs that [his] patients are either personally abusing or diverting controlled substances commits 'acts inconsistent with the public interest,' 21 U.S.C. 824(a)(4), even if [he] is merely gullible or naïve." *Jayam Krishna-Iyer,* 74 FR 459, 461 n.3 (2009) (citing *Paul J. Caragine, Jr.,* 63 FR 51592 (1998)). As *Caragine* explained, even "[c]areless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify revocation or denial" of an application. 63 FR at 51601. The Government did not, however, raise this theory in the Show Cause Order.

[23] As for Factor Three, there is no evidence that Applicant has been convicted of an offense "relating to the manufacture, distribution or dispensing of controlled substances." 21 U.S.C. 823(f)(3). There are, however, a number of reasons why a person who has engaged in misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and is therefore not dispositive. *Id.*

As for the Government's arguments with respect to Factor Five, I consider its contentions in my discussion of the appropriate sanction.

future misconduct.'' *Jayam Krishna-Iyer*, 74 FR 459, 463 (2009) (citing *Medicine Shoppe*, 73 FR 364, 387(2008)); *see also Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Cuong Tron Tran*, 63 FR 64280, 64283 (1998); *Prince George Daniels*, 60 FR 62884, 62887 (1995).[24]

So too, an Applicant's candor during the course of an investigation and subsequent proceeding is an important factor to be considered in determining whether he has accepted responsibility for the proven misconduct as well as the appropriate disposition of the matter. *See Robert F. Hunt*, 75 FR 49995, 50004 (2010); *Jeri Hassman*, 75 FR 8194, 8236 (2010); *see also Hoxie* v. *DEA*, 419 F.3d 477, 483 (6th Cir. 2005) (''Candor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a physician's registration is consistent with the public interest.'').

While an applicant must accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct in order to establish that its registration is consistent with the public interest, DEA has repeatedly held that these are not the only factors that are relevant in determining the appropriate disposition of the matter. *See, e.g., Joseph Gaudio*, 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer*, 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman*, 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell*, 76 FR 44359, 44369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens*, 74 FR 36751, 36757 n.22 (2009).

So too, the Agency can consider the need to deter similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio*, 74 FR at 10095 (quoting *Southwood*, 71 FR at 36503). *Cf. McCarthy* v. *SEC*, 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

Having reviewed Respondent's Position Statement, I conclude that he has failed to produce sufficient evidence to show why he should be entrusted with a new registration. With respect to his acceptance of responsibility, Respondent states only that he ''accepts full responsibility for his actions that lead [sic] to the sanctions imposed by Arizona'' and ''regrets and acknowledges that he prescribed controlled substances in Colorado while his modification request was pending.'' GX 5, at 7–8. Putting aside that the credibility of Respondent's statement cannot be tested through cross-examination because Respondent waived his right to a hearing, it is notable that Respondent does not acknowledge that he materially falsified his March 2013 application for registration in Tennessee. Respondent's failure to acknowledge his misconduct in this regard is fatal to his application.

Moreover, even with respect to his misconduct in prescribing controlled substances in Colorado, I conclude that Respondent has not adequately acknowledged his misconduct. Even putting aside that ignorance of the law is no excuse, Respondent's statement regarding his actions is less than forthcoming. As found above, Respondent asserted that ''[a]s soon as I understood my mistake, I immediately stopped prescribing controlled substances.'' Yet the evidence shows that on December 1, 2014, the DI phoned him and told him that he lacked authority to issue controlled substance prescriptions in Colorado. While this should have been the point at which he ''understood [his] mistake'' and ''immediately stopped prescribing,'' the evidence shows that Respondent issued additional controlled substance prescriptions thereafter. In short, Respondent's assertion is clearly false and I therefore also find that he has not accepted responsibility for his prescribing in Colorado when he lacked a DEA registration.

Likewise, while Respondent contends that he prescribed controlled substances in violation of the first Arizona order because he ''did not fully understand the scope of my initial restriction, which caused [him] to inadvertently violate that restriction,'' having reviewed that Order, I conclude that it was more than clear. *See* GX 8, at 4 (''IT IS HEREBY FURTHER ORDERED that [Respondent], holder of osteopathic medical License number 2686 is restricted from prescribing or recommending Schedule I, II, III, or IV controlled substances for a period of two (2) years from the effective date of this Order.''). Indeed, if Respondent did not fully understand the scope of the restriction, he had five weeks to contact the Board and clarify his understanding before the Order went into effect. Nor is Respondent's explanation credible given that he continued prescribing and issuing dispensing orders even after he surrendered his DEA registration. I thus conclude that Respondent has not credibly acknowledged his misconduct.

I also conclude that the record as a whole establishes that Respondent's misconduct was egregious given his material falsification of his March 2013 DEA application, his prescribing of controlled substances after the Arizona Board's Order became effective, and his continued prescribing in Arizona after he surrendered his DEA registration. As for his prescribing in Colorado, even were I to accept his excuse that he mistakenly believed that he could prescribe once he submitted his request for modification, his issuance of prescriptions after he was told by the DI that he lacked authority to write prescriptions in the State renders this misconduct egregious as well.

Accordingly, I find that Respondent's misconduct warrants denial of his application for this reason as well. So too, I find that the Agency's interest in deterring similar misconduct by other applicants who may contemplate materially falsifying their applications, as well as by other registrants who may choose to ignore agency regulations and prescribe when they lack authority to do so, supports the denial of his application.

Of further note, as explained in my discussion of Factor One, subsequent to the issuance of the Show Cause Order and Respondent's submission of his Position Statement, the Colorado Medical Board suspended his medical license and his license remains suspended as of the date of this Order. As a consequence, Respondent no longer holds authority under state law to dispense controlled substances in the State where he is currently registered and thus no longer meets the statutory prerequisite for obtaining and maintaining his registration. *See Frederick Marsh Blanton*, 43 FR 27616, 27617 (1978) (''State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.''); *see also* 21 U.S.C. 823(f) (''The Attorney General shall register practitioners . . .

---

[24] This rule also applies to other grounds that support the denial of an application, such as where the Government has proven that an applicant materially falsified his application. *See Jackson*, 72 FR, at 23853.

if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.''); 21 U.S.C. 802(21) (''[t]he term 'practitioner' means a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice'').[25]

While the Show Cause Order did not assert this as a ground for denial of his application (because it occurred subsequent to the issuance of the Order), the Government did serve a copy of its Addendum which presented this development to me, on Respondent. In response to this filing, Respondent has raised no objection.[26] In any event, there are two other independent and legally sufficient bases to deny his application. Accordingly, I will deny his application.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Richard J. Settles, for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This Order is effective immediately.

Dated: September 13, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–22680 Filed 9–20–16; 8:45 am]

BILLING CODE 4410–09–P

---

[25] *See also Rezik A. Saqer,* 81 FR 22122, 22125–27 (2016); *Sheran Arden Yeates,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci,* 58 FR 51104, 51105 (1993); *Bobby Watts,* 53 FR 11919, 11920 (1988).

[26] DEA has previously held that ''[t]he rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence. The Government's failure to file an amended Show Cause Order alleging that Respondent's state CDS license has expired does not render the proceeding fundamentally unfair.'' *Roy E. Berkowitz,* 74 FR 36758, 36759–60 (2009); *see also Hatem M. Ataya,* 81 FR 8221, 8245 (2016) (collecting cases).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Nanosyn, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before November 21, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on December 18, 2015, Nanosyn, Inc., Nanoscale Combinatorial Synthesis, 3331–B Industrial Drive, Santa Rosa, California 95403 applied to be registered as a bulk manufacturer the of following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Oxymorphone	9652	II
Fentanyl	9801	II

The company is a contract manufacturer. At the request of the company's customers, it manufacturers derivatives of controlled substances in bulk form.

Dated: September 15, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–22737 Filed 9–20–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Kevin L. Lowe, M.D.; Decision and Order

On May 18, 2016, Chief Administrative Law Judge John J. Mulrooney, II (CALJ), issued the attached Recommended Decision (R.D.).[1] Therein, the CALJ found that it is undisputed that Respondent is currently without authority to handle controlled substances in New York, the State in which he holds DEA Registration FL2580163. R.D. at 4. The CALJ thus granted the Government's Motion for Summary Disposition and recommended that I revoke Respondent's registration and deny any pending applications.

Neither party filed exceptions to the Recommended Decision. Having reviewed the record, I adopt the CALJ's finding that Respondent lacks state authority to handle controlled substances in New York, the State in which he is registered. ''State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.'' *Frederick Marsh Blanton,* 43 FR 27616, 27617 (1978). *See also Rezik A. Saqer,* 81 FR 22122, 22124–127 (2016). Thus, once the Government establishes that an applicant for a practitioner's registration or a practitioner-registrant does not possess state authority, there are no further facts to be considered and revocation is the mandatory sanction that must be entered under the Controlled Substances Act. Accordingly, I will also adopt the CALJ's recommendation that I revoke Respondent's registration and deny any pending application to renew or modify his registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FL2580163 issued to Kevin L. Lowe, M.D., be, and it hereby is, revoked. I further order that any pending application of Kevin L. Lowe, M.D., to renew or modify the above registration, be, and it hereby is, denied. This Order is effective immediately.[2]

---

[1] All citations to the Recommended Decision are to the slip opinion issued by the CALJ.

[2] Based on Respondent's acknowledgment that he has been convicted of conspiring to unlawfully distribute controlled substances, *see* Resp.'s Hrng. Req., at 1–2, I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

Dated: September 14, 2016.

Chuck Rosenberg,

Acting Administrator.

Order Granting the Government's Motion for Summary Disposition and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

Chief Administrative Law Judge John J. Mulrooney, II. The Deputy Assistant Administrator, Drug Enforcement Administration (DEA), issued an Order to Show Cause (OSC), dated March 28, 2016, proposing to revoke the DEA Certificate of Registration (COR), Number FL2580163,[3] of Kevin L. Lowe, M.D. (Respondent), pursuant to 21 U.S.C. 824(a)(3) and 21 U.S.C. 823(f). In the OSC, the DEA avers that the Respondent's lack of "authority to handle controlled substances in the State of New York, the state in which [the Respondent is] registered with the DEA," is a basis for revocation of the Respondent's COR.[4]

The Respondent, *pro se,* timely filed a Request for Hearing dated April 3, 2016,[5] wherein he conceded that he is currently without state authority to handle controlled substances. *See* Req. for Hr'g at 1 (stating that his "imprisonment has prevented [him] from renewing his state license"). The Respondent also maintained that he is innocent of the crime for which he was convicted and is in the process of appealing his conviction. *Id.* at 1, 3.

On April 22, 2016, the Government filed a Motion for Summary Disposition, seeking a Recommended Decision granting the Government's Motion because Respondent is currently without authority to handle controlled substances in New York. Gov't Mot. at 1. Appended to its Motion, the Government provided a Certification by Cathy Hanczaryk, legal custodian of the official records of the Division of Professional Licensing Services of the New York State Education Department, in which Ms. Hanczaryk attests that the Respondent "is not currently registered to practice the profession [of medicine] in New York" and has not been so registered since October 31, 2015. Gov't Mot. App'x B. Ms. Hanczaryk's Certification further states that the Respondent "has not filed a registration renewal application for the period of" November 1, 2015 to October 31, 2017. *Id.* According to a supporting Declaration by Diversion Investigator (DI) Chante Jones, also appended to the Government's Motion, DI Jones personally obtained the Certification by Ms. Hanczaryk after learning that the Respondent, who had been convicted in federal district court, did not have an active license to practice medicine in New York and has been without one since October 31, 2015. Gov't Mot. App'x C at 1–2.

The Respondent's reply to the Government's motion was due on May 11, 2016.[6] Having afforded an additional week of time in the event that the Respondent's reply was mailed but not timely, the Government's motion would appropriately be granted as unopposed. Even without doing so, however, the Government's motion must be granted on the existing record.

In order to revoke a registrant's DEA registration, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e). Once the DEA has made its *prima facie* case for revocation of the registrant's DEA COR, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's COR would not be appropriate. *Morall* v. *DEA,* 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72311, 72312 (1980).

The Controlled Substances Act (CSA) requires that, in order to maintain a DEA registration, a practitioner must be authorized to handle controlled substances in the state in which he practices. *See* 21 U.S.C. 823(f) ("The Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices."); *see also* 21 U.S.C. 802(21) (the CSA defines "practitioner" as "a physician . . . licensed, registered, or otherwise permitted, . . . by the jurisdiction in which he practices . . . to . . . dispense [or] administer . . . a controlled substance in the course of professional practice"). DEA has long held that possession of authority under state law to dispense controlled substances is not only a prerequisite to obtaining a registration, but also an essential condition for maintaining one. *Serenity Café,* 77 FR 35027, 35028 (2012); *David W. Wang, M.D.,* 72 FR 54297, 54298 (2007); *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988). Because "possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration," this Agency has consistently held that "the CSA requires the revocation of a registration issued to a practitioner who lacks [such] authority." *John B. Freitas, D.O.,* 74 FR 17524, 17525 (2009); *see James Alvin Chaney, M.D.,* 80 FR 57391, 57391 (2015); *Scott Sandarg, D.M.D.,* 74 FR 17528, 17529 (2009); *Roy Chi Lung, M.D.,* 74 FR 20346, 20347 (2009); *Roger A. Rodriguez, M.D.,* 70 FR 33206, 33207 (2005); *Stephen J. Graham, M.D.,* 69 FR 11661, 11662 (2004); *Abraham A. Chaplan, M.D.,* 57 FR 55280, 55280–81 (1992); *see also Harrell E. Robinson, M.D.,* 74 FR 61370, 61375 (2009) (Agency revoked a registration based on loss of state authority after hearing before an ALJ, but also considered the public interest factors in its analysis); *but see* 21 U.S.C. 824(a)(3) (loss of state authority constitutes a discretionary basis for sanction, not a mandatory basis). The Agency has deemed this rule to be applicable "not only where a registrant's state authority has been suspended or revoked, but also where a practitioner with an existing DEA registration has lost his state authority for reasons other than through formal disciplinary action of a State board," such as "expiration of [a] state license." *Freitas,* 74 FR at 17525 (citing *William D. Levitt, D.O.,* 64 FR 49822, 49823 (1999)); *see Mark L. Beck, D.D.S.,* 64 FR 40899, 40900 (1999); *Charles H. Ryan, M.D.,* 58 FR 14430, 14430 (1993).

Congress does not intend for administrative agencies to perform meaningless tasks. *See Philip E. Kirk, M.D.,* 48 FR 32887 (1983), *aff'd sub nom. Kirk* v. *Mullen,* 749 F.2d 297 (6th Cir. 1984); *see also Puerto Rico Aqueduct & Sewer Auth.* v. *EPA,* 35 F.3d 600, 605 (1st Cir. 1994); *NLRB* v. *Int'l Assoc. of Bridge, Structural & Ornamental Ironworkers, AFL–CIO,* 549 F.2d 634 (9th Cir. 1977); *United States* v. *Consol. Mines & Smelting Co.,* 455 F.2d 432, 453 (9th Cir. 1971). Thus, it is well-settled that, where no genuine question of fact is involved or when the material facts are agreed upon, a plenary, adversarial administrative proceeding is not required. *See Jesus R. Juarez, M.D.,* 62 FR 14945 (1997);

---

[3] The Respondent's DEA COR is current and expires by its terms on March 31, 2017. Gov't Mot. App'x A.

[4] The OSC also alleges that the Respondent was convicted of one count of conspiracy to distribute narcotics involving oxycodone in violation of 21 U.S.C. 846. OSC at 1.

[5] Respondent apparently filed the Request for Hearing with the Office of Diversion Control, and Government counsel forwarded the request to the Office of Administrative Law Judges on April 11, 2016.

[6] The Government requested additional time to file its Motion, which was granted, and the Respondent's original due date was likewise extended.

Dominick A. Ricci, M.D., 58 FR 51104 (1993). Here, the supplied Certification by Ms. Hanczaryk establishes, and the Respondent concedes,[7] that the Respondent is currently without authorization to handle controlled substances in New York, the jurisdiction where the Respondent holds the DEA COR that is the subject of this litigation.

Summary disposition of an administrative case is warranted where, as here, "there is no factual dispute of substance." *Veg-Mix, Inc.* v. *U.S. Dep't of Agric.*, 832 F.2d 601, 607 (D.C. Cir. 1987) ("[A]n agency may ordinarily dispense with a hearing when no genuine dispute exists."). At this juncture, no genuine dispute exists over the fact that the Respondent lacks state authority to handle controlled substances in New York. Because the Respondent lacks such state authority, Agency precedent dictates that he is not entitled to maintain his DEA registration. Simply put, there is no contested factual matter adducible at a hearing that would, in the Agency's view, provide authority to allow the Respondent to continue to hold his COR.[8]

Accordingly, I hereby *Grant* the Government's Motion for Summary Disposition; and further *Recommend* that the Respondent's DEA registration be *Revoked* forthwith, and any pending applications for renewal be *Denied*.

Dated: May 18, 2016.

John J. Mulrooney, II
Chief Administrative Law Judge.

[FR Doc. 2016–22751 Filed 9–20–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[Docket No. ODAG 165]

National Commission on Forensic Science Solicitation of Applications for Additional Commission Membership To Support Medicolegal Death Investigation

AGENCY: Department of Justice.

ACTION: Solicitation of Applications for Additional Commission Membership for the National Commission on Forensic Science specifically to fill a current forensic pathologist Commissioner vacancy to support medicolegal death investigation.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, this notice announces the solicitation of applications for additional Commission membership specifically to fill a current forensic pathologist Commissioner vacancy to support medicolegal death investigation.

DATES: Applications must be received on or before October 21, 2016.

ADDRESSES: All applications should be submitted to: Jonathan McGrath, Designated Federal Official, 810 7th Street NW., Washington, DC 20531, by email at *Jonathan.McGrath@usdoj.gov.*

FOR FURTHER INFORMATION CONTACT: Jonathan McGrath, Designated Federal Official, 810 7th Street NW., Washington, DC 20531, by email *Jonathan.McGrath@usdoj.gov*, or by phone at (202) 514–6277.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. App.), this notice announces the solicitation of applications for additional Commission membership on the National Commission on Forensic Science to fill a current vacancy. The National Commission on Forensic Science was chartered on April 23, 2013 and the charter was renewed on April 23, 2015. There is currently a forensic pathologist Commissioner vacancy to support medicolegal death investigation. This notice announces the solicitation of applications for Commission membership to fill this vacancy.

The Commission is co-chaired by the Department of Justice and National Institute of Standards and Technology. The Commission provides recommendations and advice to the Department of Justice concerning national methods and strategies for: Strengthening the validity and reliability of the forensic sciences (including medico-legal death investigation); enhancing quality assurance and quality control in forensic science laboratories and units; identifying and recommending scientific guidance and protocols for evidence seizure, testing, analysis, and reporting by forensic science laboratories and units; and identifying and assessing other needs of the forensic science communities to strengthen their disciplines and meet the increasing demands generated by the criminal and civil justice systems at all levels of government. Commission membership includes Federal, State, and Local forensic science service providers; research scientists and academicians; prosecutors, defense attorneys, and judges; law enforcement; and other relevant backgrounds. The Commission reports to the Attorney General, who through the Deputy Attorney General, shall direct the work of the Commission in fulfilling its mission.

The duties of the Commission include: (a) Recommending priorities for standards development; (b) reviewing and recommending endorsement of guidance identified or developed by subject-matter experts; (c) developing proposed guidance concerning the intersection of forensic science and the courtroom; (d) developing policy recommendations, including a uniform code of professional responsibility and minimum requirements for training, accreditation and/or certification; and (e) identifying and assessing the current and future needs of the forensic sciences to strengthen their disciplines and meet growing demand.

Members will be appointed by the Attorney General in consultation with the Director of the National Institute of Standards and Technology and the vice-chairs of the Commission. Additional members will be selected to fill vacancies to maintain a balance of perspective and diversity of experiences, including Federal, State, and Local forensic science service providers; research scientists and academicians; Federal, State, Local prosecutors, defense attorneys and judges; law enforcement; and other relevant stakeholders. DOJ encourages submissions from applicants with respect to diversity of backgrounds, professions, ethnicities, gender, and geography. The Commission shall consist of approximately 30 voting members. Members will serve without compensation. The Commission generally meets four times each year at approximately three-month intervals. Additional information regarding the Commission can be found at: *http://www.justice.gov/ncfs.*

Applications: Any qualified person may apply to be considered for appointment to this advisory committee. Each application should include: (1) A resume or curriculum vitae; (2) a statement of interest describing the applicant's relevant experience; and (3) a statement of support from the applicant's employer. Potential candidates may be asked to provide detailed information as necessary regarding financial interests, employment, and professional affiliations to evaluate possible sources of conflicts of interest. The application period will remain open through October 21, 2016. The applications must be sent in one complete package, by email, to Jonathan McGrath (contact information above) with the subject line of the email entitled, "NCFS

---

[7] The Respondent conceded his lack of state authority in his Request for Hearing. Req. for Hr'g at 1 (stating that his "imprisonment has prevented [him] from renewing his state license").

[8] However, should the Respondent's state authority be renewed, he may apply for a new DEA COR. *See Franklyn Seabrooks, M.D.*, 79 FR 44196, 44197 n.1 (2014).

Membership 2016.'' Other sources, in addition to the **Federal Register** notice, may be utilized in the solicitation of applications.

Dated: September 15, 2016.

Victor Weedn,

Senior Forensic Advisor to the Deputy Attorney General, U.S. Department of Justice.

[FR Doc. 2016–22715 Filed 9–20–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Labor Standards for Federal Service Contracts

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Wage and Hour Division (WHD) sponsored information collection request (ICR) titled, ''Labor Standards for Federal Service Contracts,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 21, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201603-1235-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–WHD, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Labor Standards for Federal Service Contracts information collection. The WHD administers the McNamara-O'Hara Service Contract Act (SCA), 41 U.S.C. 6701 *et seq.* The SCA applies to every contract entered into by the United States or the District of Columbia, the principal purpose of which is to furnish services to the United States through the use of service employees. The SCA requires contractors and subcontractors performing services on covered Federal or District of Columbia contracts in excess of $2,500 to pay service employees in various classes no less than the monetary wage rates and to furnish fringe benefits found prevailing in the locality, or the rates (including prospective increases) contained in a predecessor contractor's collective bargaining agreement. Safety and health standards also apply to such contracts. The WHD administers and enforces SCA compensation requirements. This ICR is to continue PRA authorization the following information collection requirements: (1) Vacation Benefit Seniority List, (2) Conformance Record, and (3) Submission of Collective Bargaining Agreement. SCA section 2(a) authorizes this information collection. *See* 41 U.S.C. 6703.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1235–0007.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on October 31, 2016. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 21, 2016 (81 FR 15131).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1235–0007. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–WHD.

Title of Collection: Labor Standards for Federal Service Contracts.

OMB Control Number: 1235–0007.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 77,141.

Total Estimated Number of Responses: 77,141.

Total Estimated Annual Time Burden: 76,213 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: September 15, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–22687 Filed 9–20–16; 8:45 am]

BILLING CODE 4510–27–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Advisory Board on Toxic Substances and Worker Health

AGENCY: Office of Workers' Compensation Programs.

ACTION: Announcement of meeting of the Advisory Board on Toxic Substances and Worker Health (Advisory Board) for the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).

SUMMARY: The Advisory Board will meet October 17–19, 2016, in Oak Ridge, Tennessee.

Comments, requests to speak, submissions of materials for the record, and requests for special accommodations: You must submit (postmark, send, transmit) comments, requests to address the Advisory Board, speaker presentations, and requests for special accommodations for the meetings by October 7, 2016.

ADDRESSES: The Advisory Board will meet at the Comfort Inn Oak Ridge, 433 Rutgers Ave., Oak Ridge, Tennessee 37830, phone 865–481–8200.

Submission of comments, requests to speak and submissions of materials for the record: You may submit comments, materials, and requests to speak at the Advisory Board meeting, identified by the Advisory Board name and the meeting date of October 17–19, 2016, by any of the following methods:

- *Electronically:* Send to: *EnergyAdvisoryBoard@dol.gov* (specify in the email subject line, for example "Request to Speak: Advisory Board on Toxic Substances and Worker Health").
- *Mail, express delivery, hand delivery, messenger, or courier service:* Submit one copy to the following address: U.S. Department of Labor, Office of Workers' Compensation Programs, Advisory Board on Toxic Substances and Worker Health, Room S–3522, 200 Constitution Ave. NW., Washington, DC 20210.

Requests for special accommodations: Please submit requests for special accommodations to attend the Advisory Board meeting by email, telephone, or hard copy to Ms. Carrie Rhoads, OWCP, Room S–3524, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210; telephone (202) 343–5580; email *EnergyAdvisoryBoard@dol.gov.*

Instructions: Your submissions must include the Agency name (OWCP), the committee name (the Advisory Board), and the meeting date (October 17–19, 2016). Due to security-related procedures, receipt of submissions by regular mail may experience significant delays. For additional information about submissions, see the **SUPPLEMENTARY INFORMATION** section of this notice.

OWCP will make available publically, without change, any comments, requests to speak, and speaker presentations, including any personal information that you provide. Therefore, OWCP cautions interested parties against submitting personal information such as Social Security numbers and birthdates.

FOR FURTHER INFORMATION CONTACT: For press inquiries: Ms. Amanda McClure, Office of Public Affairs, U.S. Department of Labor, Room S–1028, 200 Constitution Ave. NW., Washington, DC 20210; telephone (202) 693–4672; email *mcclure.amanda.c@dol.gov.*

SUPPLEMENTARY INFORMATION: Advisory Board meeting: The Advisory Board will meet Monday, October 17, 2016, from 3:00 p.m. to 5:00 p.m.; Tuesday, October 18, 2016 from 8:30 a.m. to 6:00 p.m.; and Wednesday, October 19, 2016, from 8:30 p.m. to 2:00 p.m. in Oak Ridge, Tennessee. Some Advisory Board members may attend the meeting by teleconference. The teleconference number and other details for participating remotely will be posted on the Advisory Board's Web site, *http://www.dol.gov/owcp/energy/regs/compliance/AdvisoryBoard.htm,* 72 hours prior to the commencement of the first meeting date. Advisory Board meetings are open to the public.

Public comment sessions: Tuesday, October 18, 2016, from 5:00 p.m. to 6:00 p.m.; and Wednesday, October 19, 2016, from 1:00 p.m. to 2:00 p.m. Please note that the public comment sessions end at the time indicated or following the last call for comments, whichever is earlier. Members of the public who wish to provide public comments should plan to attend the public comment session (in person or remotely) at the start time listed.

The Advisory Board is mandated by Section 3687 of EEOICPA. The Secretary of Labor established the Board under this authority and Executive Order 13699 (June 26, 2015). The purpose of the Advisory Board is to advise the Secretary with respect to: (1) The Site Exposure Matrices (SEM) of the Department of Labor; (2) medical guidance for claims examiners for claims with the EEOICPA program, with respect to the weighing of the medical evidence of claimants; (3) evidentiary requirements for claims under Part B of EEOICPA related to lung disease; and (4) the work of industrial hygienists and staff physicians and consulting physicians of the Department of Labor and reports of such hygienists and physicians to ensure quality, objectivity, and consistency. The Advisory Board sunsets on December 19, 2019.

The Advisory Board operates in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and its implementing regulations (41 CFR part 102–3).

Agenda: The tentative agenda for the Advisory Board meeting includes:

- Status of requests for information from the Department of Labor from the April 26–28, 2016 Advisory Board meeting;
- Discussion by the Subcommittee on the Site Exposure Matrices (SEM) of the Department of Labor;
- Discussion by the Subcommittee on Medical Advice for Claims Examiners re: Weighing Medical Evidence;
- Discussion by the Subcommittee on Evidentiary Requirements for Part B Lung Conditions;
- Discussion by the Subcommittee on Industrial Hygienists and Contract Medical Consultants and Their Reports;
- Advisory Board role in presumptions in EEOICPA;
- Circular 15–06 and associated memorandum regarding post-1995 exposures, and
- Update on proposed DEEOIC regulations;
- Administrative issues raised by Advisory Board functions and future Advisory Board activities; and
- Public comments.

OWCP transcribes and prepares detailed minutes of Advisory Board meetings. OWCP posts the transcripts and minutes on the Advisory Board Web page, *http://www.dol.gov/owcp/energy/regs/compliance/AdvisoryBoard.htm,* along with written comments, speaker presentations, and other materials submitted to the Advisory Board or presented at Advisory Board meetings.

Public Participation, Submissions and Access to Public Record

Advisory Board meetings: All Advisory Board meetings are open to the public. Information on how to participate in the meeting remotely will be posted on the Advisory Board's Web site.

Individuals requesting special accommodations to attend the Advisory Board meeting should contact Ms. Rhoads.

Submission of comments: You may submit comments using one of the methods listed in the **ADDRESSES** section. Your submission must include the Agency name (OWCP) and date for this Advisory Board meeting (October

17–19, 2016). OWCP will post your comments on the Advisory Board Web site and provide your submissions to Advisory Board members.

Because of security-related procedures, receipt of submissions by regular mail may experience significant delays.

Requests to speak and speaker presentations: If you want to address the Advisory Board at the meeting you must submit a request to speak, as well as any written or electronic presentation, by October 7, 2016, using one of the methods listed in the **ADDRESSES** section. Your request may include:

- The amount of time requested to speak;
- The interest you represent (*e.g.,* business, organization, affiliation), if any; and
- A brief outline of the presentation.

PowerPoint presentations and other electronic materials must be compatible with PowerPoint 2010 and other Microsoft Office 2010 formats. The Advisory Board Chair may grant requests to address the Board as time and circumstances permit.

Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This notice, as well as news releases and other relevant information, are also available on the Advisory Board's Web page at *http://www.dol.gov/owcp/energy/regs/compliance/AdvisoryBoard.htm.*

FOR FURTHER INFORMATION CONTACT: You may contact Antonio Rios, Designated Federal Officer, Advisory Board on Toxic Substances and Worker Health, Office of Workers' Compensation Programs, at *rios.antonio@dol.gov,* or Carrie Rhoads, Office of Workers' Compensation Programs, at *rhoads.carrie@dol.gov,* U.S. Department of Labor, 200 Constitution Ave. NW., Suite S–3524, Washington, DC 20210, telephone (202) 343–5580. This is not a toll-free number.

Signed at Washington, DC, this 15th day of September, 2016.

Leonard J. Howie III,

Director, Office of Workers' Compensation Programs.

[FR Doc. 2016–22712 Filed 9–20–16; 8:45 am]

BILLING CODE 4510–24–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0201]

Nuclear Power Plant Instrumentation for Earthquakes

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft regulatory guide (DG)–1332, "Nuclear Power Plant Instrumentation for Earthquakes." This DG is proposed Revision 3 of Regulatory Guide 1.12, "Nuclear Power Plant Instrumentation for Earthquakes." The NRC proposes to revise the guide to incorporate advances in seismic instrumentation and operating experience since Revision 2 of RG 1.12 was issued in 1997. The proposed revision describes the seismic instrumentation criteria, including instrumentation type, locations, characteristics, and maintenance, that the NRC staff considers acceptable for nuclear power plants.

DATES: Submit comments by November 21, 2016. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0201. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Sarah Tabatabai, telephone: 301–415–2982, email: *Sarah.Tabatabai@nrc.gov;* and Edward O'Donnell, telephone: 301–415–3317, email: *Edward.ODonnell@nrc.gov.* Both are staff of the Office of Nuclear Regulatory Research of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0201 when contacting the NRC about the availability of information regarding this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0201.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The DG is available in ADAMS under Accession No. ML16104A220.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0201 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as enters the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Additional Information

The NRC is issuing for public comment a DG in the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses.

The DG entitled, "Nuclear Power Plant Instrumentation for Earthquakes," is proposed Revision 3 of RG 1.12, "Nuclear Power Plant Instrumentation for Earthquakes." The DG is temporarily identified by its task number, DG–1332. The guide proposes revised guidance for the seismic instrumentation criteria, including instrumentation type, locations, characteristics, and maintenance, that the NRC staff considers acceptable for nuclear power plants. The current revision of RG 1.12 dates to 1997 and significant technological advances in seismic instrumentation have since been made. Lessons learned from the recent earthquakes that impacted the North Anna and Fukushima-Dai-ichi nuclear power plants indicate a need to update seismic instrumentation guidance relative to instrument characteristics, locations, installation, and maintenance. In addition, the guide needs to be reformatted to align with the current program guidance for regulatory guides.

III. Backfitting and Issue Finality

This DG describes the seismic instrumentation criteria, including instrumentation type, locations, characteristics, and maintenance, that the NRC staff considers acceptable for nuclear power plants. Issuance of this DG, if finalized, would not constitute backfitting as defined in § 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR) (the Backfit Rule) and would not otherwise be inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the "Implementation" section of this DG, the NRC has no current intention to impose this guide, if finalized, on holders of current operating licenses or combined licenses.

This DG may be applied to applications for operating licenses, combined licenses, early site permits, and certified design rules docketed by the NRC as of the date of issuance of the final guide, as well as future applications submitted after the issuance of the guide. Such action would not constitute backfitting as defined in the Backfit Rule or be otherwise inconsistent with the applicable issue finality provision in 10 CFR part 52, inasmuch as such applicants or potential applicants are not within the scope of entities protected by the Backfit Rule or the relevant issue finality provisions in 10 CFR part 52.

Dated at Rockville, Maryland, this 16th day of September, 2016.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2016–22743 Filed 9–20–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0189]

Shipping, Receiving, and Internal Transfer of Special Nuclear Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment Draft Regulatory Guide (DG) DG–5051, "Shipping, Receiving, and Internal Transfer of Special Nuclear Material." This DG would consolidate in one document NRC guidance concerning the material control and accounting requirements pertaining to shipments, receipts, and internal transfers of special nuclear material. The DG is part of the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses.

DATES: Submit comments by October 21, 2016. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0189. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Glenn Tuttle, Office of Nuclear Material Safety and Safeguards, 301–415–7230, email: *Glenn.Tuttle@nrc.gov,* or Mekonen Bayssie, Office of Nuclear Regulatory Research, 301–415–1699, email: *Mekonen.Bayssie@nrc.gov,* U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0189 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0189.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.* " For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0189 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Additional Information

The DG is entitled, "Shipping, Receiving, and Internal Transfer of Special Nuclear Material," and would provide guidance for meeting the nuclear material control and accounting (MC&A) requirements in part 74 of title 10 of the *Code of Federal Regulations* (10 CFR), "Material Control and Accounting of Special Nuclear Material," that cover these topics. The DG is electronically available in ADAMS under Accession No. ML14181B213. The DG is temporarily identified by its task number, DG–5051.

DG–5051 updates and combines in one document guidance previously provided by:

- RG 5.28, "Evaluation of Shipper-Receiver Differences in the Transfer of Special Nuclear Material," published in June 1974 (ADAMS Accession No. ML003740063);
- RG 5.49, "Internal Transfers of Special Nuclear Material," published in March 1975 (ADAMS Accession No. ML003739222); and
- RG 5.57, "Shipping and Receiving Control of Strategic Special Nuclear Material," published in June 1980 (ADAMS Accession No. ML003739260).

Due to several rulemakings that occurred from 1985 to 2002, which significantly amended the MC&A requirements, the above regulatory guides became outdated as they no longer cite the correct sections of the regulations. Accordingly, RG 5.28, RG 5.49, and RG 5.57 would be withdrawn concurrent with any later issuance of DG–5051 in final form as DG–5051 would provide the correct citations to the 10 CFR part 74 regulations.

NRC guidance on the MC&A requirements pertaining to shipments, receipts, and internal transfers of special nuclear material is also provided in the following NUREGs that were issued in conjunction with the 1985–2002 MC&A rulemakings:

- NUREG–1280, "Standard Format and Content Acceptance Criteria for the Material Control and Accounting (MC&A) Reform Amendment," applicable to facilities using formula quantities of strategic SNM (ADAMS Accession No. ML031340295).
- NUREG–1065, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities," applicable to fuel fabrication facilities using low-enriched uranium (ADAMS Accession No. ML031340288).
- NUREG/CR–5734, "Recommendations to the NRC on Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Enrichment Facilities," applicable to uranium enrichment plants (ADAMS Accession No. ML15120A354).

DG–5051 incorporates guidance from these NUREGs that relates to the monitoring of shipments, receipts, and internal transfers of SNM. In addition to providing guidance on these topics, the NUREGs listed above cover other MC&A requirements as well. Accordingly, these NUREGs would not be withdrawn when DG–5051 is issued in final form.

III. Backfitting

Issuance of DG–5051 in final form would not constitute backfitting as defined in 10 CFR 70.76. As discussed in the "Implementation" section of DG–5051, the NRC has no current intention to impose this guidance on holders of part 70 licenses. Additionally, DG–5051 would incorporate relevant guidance from NUREG–1280, NUREG–1065, and NUREG/CR–5734 without making substantive changes to that guidance and update the outdated NRC guidance provided in RG 5.28, RG 5.49, and RG 5.57 by providing the correct citations to the existing 10 CFR part 74 regulations. Accordingly, the issuance of this guidance in final form would not constitute a "new" or "different" staff position within the definition of "backfitting" in 10 CFR 70.76.

Dated at Rockville, Maryland, this 15th day of September 2016.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2016–22634 Filed 9–20–16; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

3206–0032, Self-Certification of Full-Time School Attendance For The School Year, RI 25–14 and Information and Instructions for Completing the Self-Certification of Full-Time School Attendance For The School Year, RI 25–14A

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an extension, without change, of a currently approved information collection request (ICR) 3206–0032, Self-Certification of Full-Time School Attendance For The School Year, RI 25–14 and Information and Instructions for Completing the Self-Certification of Full-Time School Attendance For The School Year, RI 25–14A. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection.

DATES: Comments are encouraged and will be accepted until November 21, 2016. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the U.S. Office of Personnel Management, Retirement Services, 1900 E Street NW., Room 2347E, Washington, DC 20415, Attention: Alberta Butler or sent via electronic mail to *Alberta.Butler@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the U.S. Office of Personnel Management, Retirement Services Publications Team, 1900 E Street NW., Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910.

SUPPLEMENTARY INFORMATION: Form RI 25–14 is used to survey survivor annuitants who are between the ages of 18 and 22 to determine if they meet the requirements of Section 8341(a)(4)(C), and Section 8441, title 5, U.S.C., to receive benefits as a student. Form RI 25–14A provides instructions for completing the Self-Certification of Full-Time School Attendance For The School Year survey form. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Self-Certification of Full-Time School Attendance For The School Year and Information and Instructions for Completing the Self-Certification of Full-Time School Attendance For The School Year.

OMB Number: 3206–0032.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 14,000.

Estimated Time per Respondent: 12 minutes.

Total Burden Hours: 2,800.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2016–22753 Filed 9–20–16; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

3206–0216, We Need Important Information About Your Eligibility for Social Security Disability Benefits, RI 98–7

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on an extension, without change, of a currently approved information collection request (ICR) OMB No. 3206–0216, We Need Important Information About Your Eligibility for Social Security Disability Benefits, RI 98–7. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection.

DATES: Comments are encouraged and will be accepted until November 21, 2016. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the U.S. Office of Personnel Management, Retirement Services, 1900 E Street NW., Room 2347E, Washington, DC 20415–3500, Attention: Alberta Butler or sent via electronic mail to *Alberta.Butler@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the U.S. Office of Personnel Management, Retirement Services Publications Team, 1900 E Street NW., Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910.

SUPPLEMENTARY INFORMATION: Form RI 98–7 is used by OPM to verify receipt of Social Security Administration (SSA) disability benefits, to lessen or avoid overpayment to Federal Employees Retirement System (FERS) disability retirees. It notifies the annuitant of the responsibility to notify OPM if SSA benefits begin and the overpayment that will occur with the receipt of both benefits. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: We Need Important Information About Your Eligibility for Social Security Disability Benefits.

OMB Number: 3206–0216.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 4,300.

Estimated Time per Respondent: 5 minutes.

Total Burden Hours: 358.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2016–22755 Filed 9–20–16; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

3206–0235, Letter Reply To Request for Information, RI 20–64; Former Spouse Survivor Annuity Election, RI 20–64A; Information on Electing a Survivor Annuity for Your Former Spouse, RI 20–64B

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on an extension, without change, of a currently approved information collection request, (ICR) OMB No. 3206–0235, Letter Reply to Request for Information, Form RI 20–64 and Information on Electing a Survivor Annuity for Your Former Spouse, Form

RI 20–64A. As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection.

DATES: Comments are encouraged and will be accepted until November 21, 2016. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the U.S. Office of Personnel Management, 1900 E Street NW., Washington, DC 20415, Attention: Alberta Butler, Room 2347E or sent via electronic mail to *Alberta.Butler@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW., Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of OPM, including whether the information will have practical utility;
2. Evaluate the accuracy of OPM's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Form RI 20–64, Letter Reply to Request for Information, is used by the Civil Service Retirement System (CSRS) to provide information about the amount of annuity payable after a survivor reduction, to explain the annuity reductions required to pay for the survivor benefit, and to give the beginning rate of survivor annuity. Form RI 20–64A, Former Spouse Survivor Annuity Election, is used by the CSRS to obtain a survivor benefits election from annuitants who are eligible to elect to provide survivor benefits for a former spouse. Form RI 20–64B, Information on Electing a Survivor Annuity for Your Former Spouse, is a pamphlet that provides important information to retirees under the CSRS who want to provide a survivor annuity for a former spouse.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Letter Reply to Request for Information; Former Spouse Survivor Annuity Election.

OMB Number: 3206–0235.

Frequency: On occasion.

Affected Public: Individual or Households.

Number of Respondents: 38.

Estimated Time per Respondent: 45 minutes for RI 20–64A and 8 minutes for RI 20–64.

Total Burden Hours: 24.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2016–22757 Filed 9–20–16; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

3206–0136, Designation of Beneficiary: Federal Employees' Group Life Insurance, SF 2823

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on a revised information collection request (ICR) OMB No. 3206–0136, Designation of Beneficiary: Federal Employees' Group Life Insurance, SF 2823. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection.

DATES: Comments are encouraged and will be accepted until November 21, 2016. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the U.S. Office of Personnel Management, Healthcare and Insurance, 1900 E Street NW., Room 3459–AK, Washington, DC 20415, Attention: Dave Johnston or sent via electronic mail to *Dave.Johnston@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the U.S. Office of Personnel Management, Retirement Services Publications Team, 1900 E Street NW., Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910.

SUPPLEMENTARY INFORMATION: Standard Form 2823 is used by any Federal employee or retiree covered by the Federal Employees' Group Life Insurance (FEGLI) Program, or an assignee who owns an insured's coverage, to instruct the Office of Federal Employees' Group Life Insurance how to distribute the proceeds of the FEGLI coverage when the statutory order of precedence does not meet his or her needs. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Designation of Beneficiary: Federal Employees' Group Life Insurance.

OMB Number: 3206–0136.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 48,000.

Estimated Time per Respondent: 15 minutes.

Total Burden Hours: 12,000.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2016–22756 Filed 9–20–16; 8:45 am]

BILLING CODE 6325–38–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2016–285, CP2016–286, and CP2016–287]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* September 23, 2016 (Comment due date applies to all Docket Nos. listed above).

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2016–285; *Filing Title:* Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* September 15, 2016; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Jennaca D. Upperman; *Comments Due:* September 23, 2016.

2. *Docket No(s).:* CP2016–286; *Filing Title:* Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 6 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* September 15, 2016; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* September 23, 2016.

3. *Docket No(s).:* CP2016–287; *Filing Title:* Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* September 15, 2016; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Curtis E. Kidd; *Comments Due:* September 23, 2016.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–22718 Filed 9–20–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 14, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add First-Class Package Service Contract 63 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–198, CP2016–282.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–22675 Filed 9–20–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Parcel Select Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 14, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Parcel Select Contract 17 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–200, CP2016–284.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–22673 Filed 9–20–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 14, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 239 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–199, CP2016–283.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–22674 Filed 9–20–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 14, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add First-Class Package Service Contract 62 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–197, CP2016–281.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–22676 Filed 9–20–16; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78849; File No. SR–BatsBZX–2016–42]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Suspension of and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Modify the Options Regulatory Fee

September 15, 2016.

I. Introduction

On July 20, 2016, Bats BZX Exchange, Inc. (the "Exchange" or "BZX") filed with the Securities and Exchange Commission (the "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to modify the Options Regulatory Fee ("ORF").[3]

In its filing, BZX proposed to amend the amount of its ORF and expand its application to non-Members.[4] The proposed rule change was immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.[5] The Commission published notice of filing of the proposed rule change in the **Federal Register** on August 5, 2016.[6] To date, the Commission has not received any comment letters on the Exchange's proposed rule change.

Pursuant to Section 19(b)(3)(C) of the Act, the Commission is hereby: (1) Temporarily suspending the proposed rule change; and (2) instituting proceedings to determine whether to approve or disapprove the proposal.

II. Summary of the Proposed Rule Change

Previously, BZX assessed a per-contract ORF on each Member for all "customer" range options transactions executed or cleared by the Member, regardless of the exchange on which the transaction occurred.[7] In BatsBZX–2016–42, BZX proposed to lower the amount of the ORF from $0.0010 to $.0008 per contract side and also expanded its application to non-Members. Specifically, BZX proposed to modify and expand the application of its ORF to include all options transactions of any Member or non-Member, regardless of the exchange on which such transaction occurs, that clear at the Options Clearing Corporation ("OCC") in the "customer" range.[8]

In support of its proposal, the Exchange stated that expanding the application of the ORF to non-Members would remove an incentive for Members to clear their trades through non-Members to avoid the obligation to pay the ORF to BZX.[9] The Exchange further stated that applying the ORF to Member and non-Member customer transactions would prevent options market participants from avoiding becoming a Member of BZX based on a desire to avoid being assessed the ORF by BZX.[10]

III. Suspension of the BZX Proposal

Pursuant to Section 19(b)(3)(C) of the Act,[11] at any time within 60 days of the date of filing of an immediately effective proposed rule change pursuant to Section 19(b)(1) of the Act,[12] the Commission summarily may temporarily suspend the change in the rules of a self-regulatory organization made thereby if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78453 (August 1, 2016), 81 FR 51954, 51955 (August 5, 2016) ("Notice"). The ORF is designed to recover a material portion of the costs to the Exchange for the supervision and regulation of Members' customer options activity. The Exchange has committed to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. *See id.* at 51955.

[4] The term "Member" refers to "any registered broker or dealer that has been admitted to membership in the Exchange." *See* BZX Rule 1.5(n).

[5] 15 U.S.C. 78s(b)(3)(A). A proposed rule change may take effect upon filing with the Commission if it is designated by the exchange as "establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization." 15 U.S.C. 78s(b)(3)(A)(ii). Although the proposed rule change was effective upon filing, BZX indicated that it would not implement the fee until August 1, 2016. *See* Notice, *supra* note 3, at 51955. On August 22, 2016, the Exchange submitted a proposed rule change to delay the implementation of the modified ORF until February 1, 2017. *See* Securities Exchange Act Release No. 78746 (September 1, 2016), 81 FR 62225 (September 8, 2016) (SR–BatsBZX–2016–52).

[6] *See* Notice, *supra* note 3, at 51954.

[7] *See id.* at 51955.

[8] *See id.* Previously, BZX applied the ORF "to each Member for all options transactions executed and cleared, or simply cleared by the Member . . . ." As proposed, BZX deleted the reference to "executed" and instead applied the ORF to all trades from any Member or non-Member that clears in the "customer" range.

[9] *See id.*

[10] *See id.*

[11] 15 U.S.C. 78s(b)(3)(C).

The Commission believes it is appropriate in the public interest to temporarily suspend BZX's proposal to assess the ORF to non-Member customer transactions and solicit comment on and evaluate further whether it is consistent with the Act and the rules and regulations thereunder that are applicable to BZX.

When exchanges file their proposed rule changes with the Commission, including fee filings like BZX's present proposal, they are required to provide a statement supporting the proposal's basis under the Act and the rules and regulations thereunder applicable to the exchange.[13] The instructions to Form 19b–4, on which exchanges file their proposed rule changes, specify that such statement "should be sufficiently detailed and specific to support a finding that the proposed rule change is consistent with [those] requirements . . . ."[14]

Among other things, exchange proposed rule changes are subject to Section 6 of the Act, including Section 6(b)(4), which requires the rules of an exchange to "provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities," and Section 6(b)(5), which requires the rules of an exchange to, among other things, be "not designed to permit unfair discrimination between customers, issuers, brokers, or dealers . . . ."[15]

In justifying its proposal, the Exchange stated in its filing that its proposal is reasonable because the ORF supports the Exchange's market surveillance programs that evaluate activity across all options markets.[16] BZX stated that it analyzes all options market activity in order to effectively meet its statutory obligation to enforce compliance by Members and their associated persons with the Act and the rules of the Exchange.[17] The Exchange also argued that the proposed rule change is equitable and not unfairly discriminatory because it would avoid market participants clearing their transactions through non-Members in order to avoid paying an ORF to BZX.[18] The Exchange further stated that applying the fee to both Member and non-Member activity will eliminate an incentive for options market participants to make exchange membership decisions based on a desire to avoid paying the ORF to BZX.[19]

The Exchange also stated that assessing an ORF on non-Members will allow it to charge an ORF on transactions that were initially submitted for clearing to a clearing broker that is a Member of BZX, but that were subsequently "flipped" to the account of a non-Member for clearing.[20]

Finally, the Exchange noted that it has heard allegations from market participants that some options exchanges may also assess an ORF on all options transactions cleared by OCC in the customer range regardless of whether such transactions are executed or cleared by an exchange Member.[21] The Commission notes, however, that no rules presently maintained by any exchange currently apply the ORF to non-Members in the manner that BZX is now proposing.[22]

In temporarily suspending the Exchange's fee change, the Commission intends to further consider whether assessing the ORF on transactions of non-Members—where no BZX Member executed or cleared the trade—is consistent with the statutory requirements applicable to a national securities exchange under the Act. In particular, the Commission will consider whether the proposed rule change satisfies the standards under the Act and the rules thereunder requiring, among other things, that an exchange's rules provide for the equitable allocation of reasonable fees among members, issuers, and other persons using its facilities; not permit unfair discrimination between customers, issuers, brokers or dealers; and do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[23]

Therefore, the Commission finds that it is appropriate in the public interest, for the protection of investors, and otherwise in furtherance of the purposes of the Act, to temporarily suspend the proposed rule changes.[24]

IV. Proceedings To Determine Whether To Approve or Disapprove the BZX Proposal

In addition to temporarily suspending the proposal, the Commission also hereby institutes proceedings pursuant to Sections 19(b)(3)(C)[25] and 19(b)(2) of the Act[26] to determine whether the Exchange's proposed rule change should be approved or disapproved. Further, pursuant to Section 19(b)(2)(B) of the Act,[27] the Commission is hereby providing notice of the grounds for disapproval under consideration. The Commission believes it is appropriate to institute disapproval proceedings at this time in view of the significant legal and policy issues raised by the proposal. Institution of disapproval proceedings does not indicate, however, that the Commission has reached any conclusions with respect to the issues involved.

As discussed above, pursuant to BZX's proposal, the Exchange would assess the ORF on Members and non-Members for all of their transactions cleared at OCC in the "customer" range. As noted above, the Act and the rules thereunder require that an exchange's rules, among other things, provide for the equitable allocation of reasonable fees among members, issuers, and other persons using its facilities; not permit unfair discrimination between customers, issuers, brokers or dealers; and not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Commission solicits comment on whether the Exchange's ORF fee proposal is consistent with these standards and whether BZX has sufficiently met its burden in presenting a statutory analysis of how its proposal meets these standards.

---

[12] 15 U.S.C. 78s(b)(1).

[13] *See* 17 CFR 240.19b–4 (Item 3 entitled "Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change").

[14] *See id.*

[15] 15 U.S.C. 78f(b)(4) and (5), respectively.

[16] *See* Notice, *supra* note 3, at 51956.

[17] *See id.*

[18] *See id.*

[19] *See id.*

[20] *See id.* at 51955.

[21] *See id.* at 51956.

[22] *See id.* at note 15 (noting that no options exchange's current rule text applies in such a manner).

[23] *See* 15 U.S.C. 78f(b)(4), (5), and (8), respectively.

[24] For purposes of temporarily suspending the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[25] 15 U.S.C. 78s(b)(3)(C). Once the Commission temporarily suspends a proposed rule change, Section 19(b)(3)(C) of the Act requires that the Commission institute proceedings under Section 19(b)(2)(B) to determine whether a proposed rule change should be approved or disapproved.

[26] 15 U.S.C. 78s(b)(2).

[27] 15 U.S.C. 78s(b)(2)(B). Section 19(b)(2)(B) of the Act also provides that proceedings to determine whether to disapprove a proposed rule change must be concluded within 180 days of the date of publication of notice of the filing of the proposed rule change. *See id.* The time for conclusion of the proceedings may be extended for up to 60 days if the Commission finds good cause for such extension and publishes its reasons for so finding, or if the exchange consents to the longer period. *See id.*

In particular, the grounds for possible disapproval under consideration include whether BZX's proposal is consistent with the following sections of the Act:

- Section 6(b)(4) of the Act, which requires that the rules of a national securities exchange "provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities;" [28]
- Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange not be "designed to permit unfair discrimination between customers, issuers, brokers, or dealers;" [29] and
- Section 6(b)(8) of the Act, which requires that the rules of a national securities exchange "not impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Act]." [30]

In particular, the Commission is considering whether a sufficient regulatory nexus exists between the Exchange and a non-Member to justify imposition of the ORF on such non-Member. If a non-Member does not execute a trade on BZX's market, or utilize the services of a Member of BZX to either execute the trade on another market or clear the trade, then the non-Member would not be utilizing the facilities of the exchange or the services of a Member of the Exchange. Further, when it initially adopted an ORF, the Exchange noted that the ORF would be "designed to recover a material portion of the costs to the Exchange of the supervision and regulation *of Members' customer options business,* including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities" [31] (emphasis added). The Commission notes, however, that the Exchange's proposed expansion of the ORF to non-Members deviates from this principle in that the exercise of an exchange's regulatory jurisdiction and the application of its fee schedule is generally confined to the exchange's Members and persons using its facilities.[32] In other words, BZX's proposal preliminarily appears to expand a fee that is specifically designed to fund the exchange's regulatory operations in part, by assessing the fee to a class of person over whom the Exchange does not have any direct regulatory responsibility or jurisdiction and who have not directly or indirectly accessed the Exchange's facilities or utilized the services of a Member of the Exchange. Accordingly, the proposal's application of the ORF to non-Members who do not use the facilities of the Exchange or the services of a Member of the Exchange may prevent the Commission from making a finding that the proposal is consistent with the Act and the rules and regulations thereunder.[33]

V. Commission's Solicitation of Comments

The Commission requests written views, data, and arguments with respect to the concerns identified above as well as any other relevant concerns. Such comments should be submitted by October 12, 2016. Rebuttal comments should be submitted by October 26, 2016. The Commission asks that commenters address the sufficiency and merit of the Exchange's statements in support of the proposal, which are set forth in the Notice,[34] in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following:

- Commenters' views on the appropriateness of an options exchange assessing an ORF on options transactions executed at an away market that are cleared by OCC in the "customer" range that are neither executed, nor cleared, by a Member of the exchange assessing the ORF;
- Commenters' views on the Exchange's assertion that "there is a strong nexus between the ORF and the Exchange's regulatory activities with respect to its Members', as well as non-Members', customer trading activity." [35];
- Commenters' views on the Exchange's argument that "[i]f the ORF did not apply to activity across markets then a non-Member would send their orders to the least cost, least regulated exchange. In addition, applying the fee to all Members' and non-Members' activity across all market [sic] will avoid options participants from terminating their membership status on or not becoming a [sic] Members of certain exchanges simply to avoid being assessed [sic] ORF." [36];
- Whether any other options exchange is currently assessing an ORF on non-Members for their options transactions that are cleared by OCC in the "customer" range in contravention to a stated rule of such exchange; and
- Finally, whether any options exchange currently assesses an ORF on a clearing member that does not ultimately clear a customer transaction, but merely transfers it to the account of a non-Member for clearance and settlement, and, if so, whether doing so is consistent with the current ORF rule text of such options exchange.

Interested persons are invited to submit written data, views, and arguments concerning the proposed rule changes, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsBZX–2016–42 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsBZX–2016–42. The file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–BatsBZX–2016–42 and should be submitted on or before October 12, 2016. Rebuttal comments should be submitted by October 26, 2016.

---

[28] 15 U.S.C. 78f(b)(4).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(8).

[31] Securities Exchange Act Release No. 74214 (February 5, 2015), 80 FR 7665 (February 11, 2015) (File No. SR–BATS–2015–08).

[32] *See, e.g.,* Section 6(b)(4), which addresses fees that an exchange charges "among its members and issuers and other persons using its facilities." 15 U.S.C. 78f(b)(4).

[33] *See* 15 U.S.C. 78s(b)(2)(C)(ii) (setting forth the standard for disapproval of a proposed rule change as follows: "The Commission shall disapprove a proposed rule change of a self-regulatory organization if it does not make a finding described in clause (i)."). Section 19(b)(2)(C)(i) provides that "[t]he Commission shall approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of [the Act] and the rules and regulations issued under [the Act] that are applicable to such organization."

[34] *See* Notice, *supra* note 3.

[35] *See* Notice, *supra* note 3, at 51955.

[36] *See id.*

VI. Conclusion

It Is Therefore Ordered, pursuant to Section 19(b)(3)(C) of the Act,[37] that File No. SR-BatsBZX–2016–42, be and hereby is, temporarily suspended. In addition, the Commission is instituting proceedings to determine whether the proposed rule change should be approved or disapproved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–22656 Filed 9–20–16; 8:45 am]

BILLING CODE 8011–01–P

---

[37] 15 U.S.C. 78s(b)(3)(C).

[38] 17 CFR 200.30–3(a)(57) and (58).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78850; File No. SR–BatsEDGX–2016–33]

Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Suspension of and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Adopt an Options Regulatory Fee

September 15, 2016.

I. Introduction

On July 20, 2016, Bats EDGX Exchange, Inc. (the "Exchange" or "EDGX") filed with the Securities and Exchange Commission (the "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt an Options Regulatory Fee ("ORF").[3]

In its filing, EDGX adopted an ORF in the amount of $0.0002 per contract and proposed to assess the fee to all "customer" range options transactions cleared by Members[4] and non-Members. The proposed rule change was immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.[5] The Commission published notice of filing of the proposed rule change in the **Federal Register** on August 5, 2016.[6] To date, the Commission has not received any comment letters on the Exchange's proposed rule change.

Pursuant to Section 19(b)(3)(C) of the Act, the Commission is hereby: (1) Temporarily suspending the proposed rule change; and (2) instituting proceedings to determine whether to approve or disapprove the proposal.

II. Summary of the Proposed Rule Change

In its proposed rule change filing, EDGX proposed to adopt an ORF in the amount of $0.0002 per contract side that it would assess on Members and non-Members. Specifically, under the proposal, EDGX would assess the ORF on all options transactions that clear at the Options Clearing Corporation ("OCC") in the "customer" range, regardless of the exchange on which the transaction occurs.[7] Under the proposal, the ORF would apply to all Member and non-Member options transactions that clear at OCC in the "customer" range.[8]

In support of its proposal, the Exchange stated that applying the ORF to non-Members would remove an incentive for Members to clear their trades through non-Members to avoid the obligation to pay the ORF to EDGX.[9] The Exchange further stated that applying the ORF to Member and non-Member customer transactions would prevent options market participants from avoiding becoming a Member of EDGX based on a desire to avoid being assessed the ORF by EDGX.[10]

III. Suspension of the EDGX Proposal

Pursuant to Section 19(b)(3)(C) of the Act,[11] at any time within 60 days of the date of filing of an immediately effective proposed rule change pursuant to Section 19(b)(1) of the Act,[12] the Commission summarily may temporarily suspend the change in the rules of a self-regulatory organization made thereby if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

The Commission believes it is appropriate in the public interest to temporarily suspend EDGX's proposal to assess the ORF to Member and non-Member customer transactions and solicit comment on and evaluate further whether it is consistent with the Act and the rules and regulations thereunder that are applicable to EDGX.

When exchanges file their proposed rule changes with the Commission, including fee filings like EDGX's present proposal, they are required to provide a statement supporting the proposal's basis under the Act and the rules and regulations thereunder applicable to the exchange.[13] The instructions to Form 19b–4, on which exchanges file their proposed rule changes, specify that such statement "should be sufficiently detailed and specific to support a finding that the proposed rule change is consistent with [those] requirements . . . ."[14]

Among other things, exchange proposed rule changes are subject to Section 6 of the Act, including Section 6(b)(4), which requires the rules of an exchange to "provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities," and Section 6(b)(5), which requires the rules of an exchange to, among other things, be "not designed to permit unfair discrimination between customers, issuers, brokers, or dealers . . . ."[15]

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78452 (August 1, 2016), 81 FR 51951 (August 5, 2016) ("Notice"). The ORF is designed to recover a material portion of the costs to the Exchange for the supervision and regulation of Members' customer options activity. The Exchange has committed to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. *See id.* at 51952.

[4] The term "Member" refers to "any registered broker or dealer that has been admitted to membership in the Exchange." *See* EDGX Rule 1.5(n).

[5] 15 U.S.C. 78s(b)(3)(A). A proposed rule change may take effect upon filing with the Commission if it is designated by the exchange as "establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization." 15 U.S.C. 78s(b)(3)(A)(ii). Although the proposed rule change was effective upon filing, EDGX indicated that it would not implement the fee until August 1, 2016. *See* Notice, *supra* note 3, at 51953. On August 22, 2016, the Exchange submitted a proposed rule change to delay the implementation of the ORF until February 1, 2017. *See* Securities Exchange Act Release No. 78745 (September 1, 2016), 81 FR 62185 (September 8, 2016) (SR–BatsEDGX–2016–48).

[6] *See* Notice, *supra* note 3, at 51951.

[7] *See id.* at 51952.

[8] *See id.*

[9] *See id.*

[10] *See id.*

[11] 15 U.S.C. 78s(b)(3)(C).

[12] 15 U.S.C. 78s(b)(1).

[13] *See* 17 CFR 240.19b–4 (Item 3 entitled "Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change").

[14] *See id.*

In justifying its proposal, the Exchange stated in its filing that its proposal is reasonable because the ORF supports the Exchange's market surveillance programs that evaluate activity across all options markets.[16] EDGX further stated that it analyzes all options market activity in order to effectively meet its statutory obligation to enforce compliance by Members and their associated persons with the Act and the rules of the Exchange.[17] The Exchange also argued that the proposed rule change is equitable and not unfairly discriminatory because it would avoid market participants clearing their transactions through non-Members in order to avoid paying an ORF to EDGX.[18] The Exchange further stated that applying the fee to both Member and non-Member activity will eliminate an incentive for options market participants to make exchange membership decisions based on a desire to avoid paying the ORF to EDGX.[19]

The Exchange also stated that assessing an ORF on non-Members will allow it to charge an ORF on transactions that were initially submitted for clearing to a clearing broker that is a Member of EDGX, but that were subsequently "flipped" to the account of a non-Member for clearing.[20]

Finally, the Exchange noted that it has heard allegations from market participants that some options exchanges may also assess an ORF on all options transactions cleared by OCC in the customer range regardless of whether such transactions are executed or cleared by an exchange Member.[21] The Commission notes, however, that no rules presently maintained by any exchange currently apply the ORF to non-Members in the manner that EDGX is now proposing.[22]

In temporarily suspending the Exchange's fee change, the Commission intends to further consider whether assessing the ORF on transactions of non-Members—where no EDGX Member executed or cleared the trade—is consistent with the statutory requirements applicable to a national securities exchange under the Act. In particular, the Commission will consider whether the proposed rule change satisfies the standards under the Act and the rules thereunder requiring, among other things, that an exchange's rules provide for the equitable allocation of reasonable fees among members, issuers, and other persons using its facilities; not permit unfair discrimination between customers, issuers, brokers or dealers; and do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[23]

Therefore, the Commission finds that it is appropriate in the public interest, for the protection of investors, and otherwise in furtherance of the purposes of the Act, to temporarily suspend the proposed rule change.[24]

IV. Proceedings To Determine Whether to Approve or Disapprove the EDGX Proposal

In addition to temporarily suspending the proposal, the Commission also hereby institutes proceedings pursuant to Sections 19(b)(3)(C)[25] and 19(b)(2) of the Act[26] to determine whether the Exchange's proposed rule change should be approved or disapproved. Further, pursuant to Section 19(b)(2)(B) of the Act,[27] the Commission is hereby providing notice of the grounds for disapproval under consideration. The Commission believes it is appropriate to institute disapproval proceedings at this time in view of the significant legal and policy issues raised by the proposal. Institution of disapproval proceedings does not indicate, however, that the Commission has reached any conclusions with respect to the issues involved.

As discussed above, pursuant to EDGX's proposal, the Exchange would assess the ORF on Members and non-Members for all of their transactions cleared at OCC in the "customer" range. As noted above, the Act and the rules thereunder require that an exchange's rules, among other things, provide for the equitable allocation of reasonable fees among members, issuers, and other persons using its facilities; not permit unfair discrimination between customers, issuers, brokers or dealers; and not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Commission solicits comment on whether the Exchange's ORF fee proposal is consistent with these standards and whether EDGX has sufficiently met its burden in presenting a statutory analysis of how its proposal meets these standards.

In particular, the grounds for possible disapproval under consideration include whether EDGX's proposal is consistent with the following sections of the Act:

- Section 6(b)(4) of the Act, which requires that the rules of a national securities exchange "provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities;"[28]
- Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange not be "designed to permit unfair discrimination between customers, issuers, brokers, or dealers;"[29] and
- Section 6(b)(8) of the Act, which requires that the rules of a national securities exchange "not impose any burden on competition not necessary or appropriate in furtherance of the purposes of [the Act]."[30]

In particular, the Commission is considering whether a sufficient regulatory nexus exists between the Exchange and a non-Member to justify imposition of the ORF on such non-Member. If a non-Member does not execute a trade on EDGX's market, or utilize the services of a Member of EDGX to either execute the trade on another market or clear the trade, then the non-Member would not be utilizing the facilities of the exchange or the services of a Member of the Exchange. Further, the Exchange notes that the ORF would be "designed to recover a material portion of the costs to the Exchange of the supervision and regulation of Members' and non-Member's customer options business, including performing routine surveillances and investigations, as well as policy, rulemaking, interpretive and enforcement activities." [31] The Commission notes, however, that the Exchange's proposed application of the ORF to non-Members raises concerns in that the exercise of an exchange's regulatory jurisdiction and the application of its fee schedule is generally confined to the exchange's Members and persons using its facilities.[32] In other words, EDGX's proposal preliminarily appears to apply a fee that is specifically designed to fund the exchange's regulatory operations in part, by assessing the fee to a class of person over whom the Exchange does not have any direct regulatory responsibility or jurisdiction and who have not directly or indirectly accessed the Exchange's facilities or utilized the services of a Member of the Exchange. Accordingly, the proposal's application of the ORF to non-Members who do not use the facilities of the Exchange or the services of a Member of the Exchange may prevent the Commission from making a finding that the proposal is consistent with the Act and the rules and regulations thereunder.[33]

---

[15] 15 U.S.C. 78f(b)(4) and (5), respectively.

[16] *See* Notice, *supra* note 3, at 51953.

[17] *See id.*

[18] *See id.*

[19] *See id.*

[20] *See id.* at 51952.

[21] *See id.* at 51953.

[22] *See id.* at note 16 (noting that no options exchange's current rule text applies in such a manner).

[23] *See* 15 U.S.C. 78f(b)(4), (5), and (8), respectively.

[24] For purposes of temporarily suspending the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[25] 15 U.S.C. 78s(b)(3)(C). Once the Commission temporarily suspends a proposed rule change, Section 19(b)(3)(C) of the Act requires that the Commission institute proceedings under Section 19(b)(2)(B) to determine whether a proposed rule change should be approved or disapproved.

[26] 15 U.S.C. 78s(b)(2).

[27] 15 U.S.C. 78s(b)(2)(B). Section 19(b)(2)(B) of the Act also provides that proceedings to determine whether to disapprove a proposed rule change must be concluded within 180 days of the date of publication of notice of the filing of the proposed rule change. *See id.* The time for conclusion of the proceedings may be extended for up to 60 days if the Commission finds good cause for such extension and publishes its reasons for so finding, or if the exchange consents to the longer period. *See id.*

[28] 15 U.S.C. 78f(b)(4).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(8).

V. Commission's Solicitation of Comments

The Commission requests written views, data, and arguments with respect to the concerns identified above as well as any other relevant concerns. Such comments should be submitted by October 12, 2016. Rebuttal comments should be submitted by October 26, 2016.

The Commission asks that commenters address the sufficiency and merit of the Exchange's statements in support of the proposal, which are set forth in the Notice,[34] in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following:

- Commenters' views on the appropriateness of an options exchange assessing an ORF on options transactions executed at an away market that are cleared by OCC in the "customer" range that are neither executed, nor cleared, by a Member of the exchange assessing the ORF;
- Commenters' views on the Exchange's assertion that "there is a strong nexus between the ORF and the Exchange's regulatory activities with respect to its Members', as well as non-Members,' customer trading activity." [35];
- Commenters' views on the Exchange's argument that "[i]f the ORF did not apply to activity across markets then a non-Member would send their orders to the least cost, least regulated exchange. In addition, applying the fee to all Members' and non-Members' activity across all market [sic] will avoid options participants from terminating their membership status on or not becoming a [sic] Members of certain exchanges simply to avoid being assessed [sic] ORF." [36];
- Whether any other options exchange is currently assessing an ORF on non-Members for their options transactions that are cleared by OCC in the "customer" range in contravention to a stated rule of such exchange; and
- Finally, whether any options exchange currently assesses an ORF on a clearing member that does not ultimately clear a customer transaction, but merely transfers it to the account of a non-Member for clearance and settlement, and, if so, whether doing so is consistent with the current ORF rule text of such options exchange.

Interested persons are invited to submit written data, views, and arguments concerning the proposed rule changes, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BatsEDGX–2016–33 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsEDGX–2016–33. The file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–BatsEDGX–2016–33 and should be submitted on or before October 12, 2016. Rebuttal comments should be submitted by October 26, 2016.

VI. Conclusion

It Is Therefore Ordered, pursuant to Section 19(b)(3)(C) of the Act,[37] that File No. SR–BatsEDGX–2016–33, be and hereby is, temporarily suspended. In addition, the Commission is instituting proceedings to determine whether the proposed rule change should be approved or disapproved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–22657 Filed 9–20–16; 8:45 am]

BILLING CODE 8011–01–P

---

[31] *See* Notice, *supra* note 3, at 51952.

[32] *See, e.g.,* Section 6(b)(4), which addresses fees that an exchange charges "among its members and issuers and other persons using its facilities." 15 U.S.C. 78f(b)(4).

[33] *See* 15 U.S.C. 78s(b)(2)(C)(ii) (setting forth the standard for disapproval of a proposed rule change as follows: "The Commission shall disapprove a proposed rule change of a self-regulatory organization if it does not make a finding described in clause (i)."). Section 19(b)(2)(C)(i) provides that "[t]he Commission shall approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of [the Act] and the rules and regulations issued under [the Act] that are applicable to such organization."

[34] *See* Notice, *supra* note 3.

[35] *See id.* at 51952.

[36] *See id.*

[37] 15 U.S.C. 78s(b)(3)(C).

[38] 17 CFR 200.30–3(a)(57) and (58).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting; Additional Item

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: To be published.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Thursday, September 22, 2016.

CHANGES IN THE MEETING: The following matters will also be considered during the 2:00 p.m. Closed Meeting scheduled for Thursday, September 22, 2016:

Adjudicatory matter

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: September 16, 2016.

Lynn M. Powalski,

Deputy Secretary.

[FR Doc. 2016–22906 Filed 9–19–16; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78855; File No. SR–NYSE–2016–31]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Granting Approval of Proposed Rule Change Amending NYSE Rule 6A To Exclude the Physical Area Within Fully Enclosed Telephone Booths Located in 18 Broad Street From the Definition of Trading Floor

September 15, 2016.

I. Introduction

On May 31, 2016, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NYSE Rule 6A ("Trading Floor") to exclude a physical area within fully enclosed telephone booths located in 18 Broad Street from the definition of Trading Floor. The proposed rule change was published for comment in the **Federal Register** on June 17, 2016.[3] On July 29, 2016, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] The Commission received no comments on the proposed rule change. This order grants approval of the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to amend NYSE Rule 6A ("Trading Floor") to exclude an area within fully enclosed telephone booths located in 18 Broad Street from the definition of "Trading Floor." Under the proposal, as discussed in more detail below, the area within the enclosed telephone booths will remain within the Exchange's broader definition of Floor under Rule 6.[6] The Exchange also proposes to revise the definition of "Trading Floor" to reflect the renaming of a portion of its physical area and relocation of where NYSE Amex-listed options are traded.[7]

The Exchange currently defines "Trading Floor" in Rule 6A to mean the restricted-access physical areas designated by the Exchange for the trading of securities, commonly known as the "Main Room," the "Blue Room," and the "Garage."[8] Rule 6A then excludes from the definition of "Trading Floor" those areas designated by the Exchange where NYSE Amex-listed options are traded, commonly known as the "Extended Blue Room," which, for the purposes of the Exchange's Rules, are referred to as the "NYSE Amex Options Trading Floor."[9]

The Exchange proposes to exclude an additional area from the definition of Trading Floor. Specifically, the proposal would exclude from the defined Trading Floor the physical area within fully enclosed telephone booths located in 18 Broad Street at the Southeast wall of the Trading Floor.[10] These telephone booths are located in a vestibule area adjacent to the 18 Broad Street elevator banks that provide access to the Trading Floor. The vestibule area is separated from the equity trading areas of the Main Room by approximately forty (40) feet and a partial physical barrier. The Exchange represents that, while inside the telephone booths, there is no visual or auditory access to activities conducted at the trading posts or by Floor Brokers.[11]

Currently Exchange members and employees of member organizations are allowed to use personal portable or wireless communication devices outside the Trading Floor, provided that such use is consistent with all other Exchange Rules and federal securities laws and rules thereunder.[12] By excluding the physical area within the fully enclosed telephone booths described herein from the definition of Trading Floor, the proposal would create an exception to restrictions that would otherwise prohibit the use of personal cellular telephones while in the telephone booths. In its filing, the Exchange states that it designed the telephone booths for use by Designated Market Makers ("DMMs") and DMMs could use this space to communicate with issuers. However, the telephone booths could be used by anyone with access to the Trading Floor, including Floor Brokers.[13] In the Exchange's view, a DMM's use of a personal cellular telephone while within a telephone booth to communicate with an issuer is no different than a DMM's use of a personal cellular telephone to communicate with an issuer from a DMM's office off the Exchange or while outside the restricted-access areas of the Floor.[14]

The Exchange states in its filing that, while in a telephone booth, a DMM would not have access to any time and place information that he or she may have at a trading post. According to the Exchange, the following aspects of the telephone booths would create privacy: (1) The closest location of any Floor Broker operations, which also contains privacy barriers, is approximately forty (40) feet from the proposed location of the telephone booths; (2) there are high arching walls with limited line and sight vision separating the telephone booths from any trading posts on the Trading Floor; and (3) the telephone booths are fully enclosed so any conversation that would occur would take place behind closed doors. The Exchange states that it "believes that the combination of these visual and acoustical barriers would substantially eliminate the risk that any conversations occurring inside the telephone booth could be overheard [and] it substantially eliminates the risk that an individual having a conversation while inside the telephone booth would be able to hear or see anything at a trading post where securities trade."[15]

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 78057 (June 13, 2016), 81 FR 39722 ("Notice").

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 78442 (July 29, 2016), 81 FR 51521 (August 4, 2016). The Commission designated September 15, 2016 as the date by which it shall approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] *See,* infra, notes 16–17 and accompanying text.

[7] *See* proposed Rule 6A.

[8] *See* NYSE Rule 6A; *see also* Securities Exchange Act Release No. 59479 (Mar. 2, 2009), 74 FR 10325 (Mar. 10, 2009) (SR–NYSE–2009–23).

[9] *See* NYSE Rule 6A.

[10] *See* proposed Rule 6A.

[11] *See* Notice, *supra* note 3, at 39722–23.

[12] *See* NYSE Rule 36, Supplementary Material .23.

[13] Currently, Floor Brokers on the Trading Floor are only allowed to use an approved telephone line or Exchange authorized and provided portable phone. *See* NYSE Rule, Supplementary Material .20 and .21.

[14] *See* Notice, *supra* note 3, at 39723.

The term "Trading Floor" is distinct from the term "Floor," which is defined as the trading Floor of the Exchange and the premises immediately adjacent thereto, such as the various entrances and lobbies of the 11 Wall Street, 18 New Street, 8 Broad Street, 12 Broad Street and 18 Broad Street Buildings, and the telephone facilities available in these locations.[16] Because the area within the fully enclosed telephone booths, while outside the "Trading Floor," would still fall within the broader definition of "Floor" under Exchange rules, the Exchange would retain jurisdiction over its members while they are within the telephone booths. The Exchange notes that it would therefore retain jurisdiction within the telephone booths to regulate conduct that is inconsistent with Exchange Rules and the federal securities laws and rules thereunder.[17]

Specifically, current Exchange restrictions governing the protection of material non-public information would continue to apply to DMMs even when off the Trading Floor and thus would apply to their communications within the telephone booths. NYSE Rule 98 ("Operation of a DMM Unit") provides that "[w]hen a Floor-based employee of a DMM unit moves to a location off of the Trading Floor of the Exchange or if any person that provides risk management oversight or supervision of the Floor-based operations of the DMM unit is aware of Floor-based non-public order information,[18] he or she shall not (1) make such information available to customers, (2) make such information available to individuals or systems responsible for making trading decisions in DMM securities in away markets or related products, or (3) use any such information in connection with making trading decisions in DMM securities in away markets or related products."[19] The Exchange, in its filing, explains that the proposed rule change is not intended to circumvent the restrictions prescribed in Rule 98 applicable to DMMs, including those pertaining to the misuse of material non-public information.[20]

NYSE Rule 36, Supplementary Material .30 ("DMM Unit Post Wires") permits DMMs to maintain telephone lines at their trading posts to communicate with personnel at the off-Floor offices of the DMM, the DMM's clearing firm, or with persons providing non-trading-related services to the DMM, and wired or wireless devices that are registered with the Exchange to communicate with the system employing the DMM's algorithms and with individual algorithms.[21] The Exchange further states in its filing that it is not proposing any changes to Rule 36 and that DMMs would continue to be subject to Supplementary Material .30 to Rule 36.[22]

Additionally, the Exchange proposes amendments to reflect the renaming and relocation of certain trading areas. The Exchange has renamed the former "Garage" as the "Buttonwood Room."[23] The Exchange also recently closed the "Blue Room" and the "Extended Blue Room" and moved all member organizations, member organization employees, and NYSE Amex Options trading activities that were previously housed in these areas to the Buttonwood Room. Therefore the proposal would delete references to the "Blue Room" and "Extended Blue Room" and replace them with references to the "Buttonwood Room."[24] The current rule excludes the NYSE Amex Options Trading Floor from the definition of Trading Floor.[25] The proposal would exclude from the definition of Trading Floor the designated areas in the Buttonwood Room where NYSE Amex-listed options are traded, which, for the purposes of the Exchange's Rules, would continue to be referred to as the "NYSE Amex Options Trading Floor."[26] The Exchange states that this proposal does not alter the substance of the rule and reflects only the location change for NYSE Amex Options.[27]

II. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[28] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[29] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange proposes to exclude from the definition of "Trading Floor" the physical area within fully enclosed telephone booths located in 18 Broad Street.[30] Through this definitional change, the proposal would allow persons within the telephone booths to use personal portable or wireless communications devices outside the Trading Floor, provided such use is consistent with all other Exchange Rules and federal securities laws and the rules thereunder.[31] The Exchange states that it designed the telephone booths for use by DMMs, and DMMs could use a personal cellular telephone within this space to communicate with issuers, but the telephone booths could also be used by anyone with access to the Trading Floor.[32]

When approving the use of personal portable or wireless communications devices outside of the Exchange's Trading Floor and other restricted access areas, the Commission found there to be a reasonable balance between the Exchange's interest in providing a convenient and comfortable space for Exchange members and member firm employees to use personal portable communications devices inside the Exchange buildings and in minimizing the risk of misuse of such devices.[33] Based on representations made by the Exchange, the Commission believes that this proposal provides a similar balance between the Exchange's interest to provide a convenient location for DMMs and others on the Trading Floor to place telephone calls while minimizing the risk of any potential time and place advantage that could come with using personal portable communication devices in proximity to trading activity.[34] While the telephone booths fall within the physical turnstiles that generally control entry onto the Trading Floor, they are separated from trading activity by approximately forty (40) feet. According to the Exchange, the location of the telephone booths, and the enclosed setting within such booths, would provide sufficient visual and auditory barriers between the area within the telephone booths and trading activity, so as to minimize the possibility of any time and place advantage.[35] The Exchange has also indicated that the glass on the telephone booths has been frosted to make it opaque, which should help further reduce any sight lines to non-public Trading Floor information.[36] Additionally, the Commission believes that given the current speed of electronic trading, any Floor-based non-public order information that the DMM, or other floor-based personnel using the telephone booths, had prior to leaving his or her trading post or booth area would likely be rendered stale by the time he or she reached the telephone booths, thereby substantially reducing the risk of any time and place advantage.

---

[15] *See* Notice, *supra* note 3, at 39723.

[16] *See* NYSE Rule 6.

[17] *See* Notice, *supra* note 3, at 39723.

[18] NYSE Rule 98(b)(4) states that "Floor-based non-public order" means "any order, whether expressed electronically or verbally, or any information regarding a reasonably imminent non-public transaction or series of transactions entered or intended for entry or execution on the Exchange and which is not publicly available on a real-time basis via an Exchange-provided datafeed, such as NYSE OpenBook® or otherwise not publicly available."

[19] *See* NYSE Rule 98(c)(3)(C). Rule 98(c)(3)(C) does not restrict communications between a DMM and the DMM's risk manager off the Trading Floor, as may be necessary if a Floor Broker needs to discuss the risk profile of a proposed transaction.

[20] *See* Notice, *supra* note 3, at 39723.

[21] *See* NYSE Rule 36, Supplementary Material .30.

[22] *See* Notice, *supra* note 3, at 39723.

[23] *See* Notice, *supra* note 3, at 39722.

[24] *See* Notice, *supra* note 3, at 39722.

[25] *See* NYSE Rule 6A.

[26] *See* proposed Rule 6A. The Exchange states that, as when the NYSE Amex Options Trading Floor was located in the Extended Blue Room, the Exchange has erected physical barriers between the NYSE Amex Options Trading Floor and any Exchange member organizations or Exchange personnel that are also located in the Buttonwood Room. *See* Notice, *supra* note 3, at 39722 n7.

[27] *See* Notice, *supra* note 3, at 39722.

[28] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[29] 15 U.S.C. 78f(b)(5).

[30] *See* proposed Rule 6A.

[31] *See* NYSE Rule 36, Commentary .23.

[32] *See* Notice, *supra* note 3, at 39723.

The Commission notes that the Exchange will retain jurisdiction over its members and member organizations, including DMM units and their employees, for their conduct within the telephone booths because this area is still within the broader definition of Floor under NYSE Rule 6.[37] With respect to DMMs in particular, NYSE Rule 98 contains restrictions on a DMM's conduct while on and off the Trading Floor. These restrictions include a general prohibition on the misuse of Floor-based non-public order information.[38] When a DMM moves to a location off the Trading Floor, the DMM must not make Floor-based non-public order information available to customers or to individuals or systems responsible for making trading decisions in DMM securities in away markets or related products, or use any such information in connection with trading decisions in DMM securities in away markets or related products.[39]

In addition, the Commission has been concerned about whether there could be a misuse of any information about customer orders or other material information that is passed to a DMM or other floor personnel through the use of personal cellular telephones within private telephone booths in close proximity to the Trading Floor. For similar reasons noted above that reduce the risk of misuse of Floor-based non-public order information,[40] such as the speed of electronic trading, and the Exchange's representations concerning its surveillance of transactions occurring on the Exchange Trading Floor, the Commission believes the Exchange has addressed these concerns.

The Exchange has represented that information DMMs and other floor-based personnel relay, receive, or discuss on personal cellular phones within the telephone booths adjacent to the Trading Floor, will not, in the Exchange's view diminish the ability of the Exchange to adequately surveil its market for the misuse of Floor-based non-public order information and other material non-public information.[41] The Commission, therefore, believes that based on the Exchange's representations noted above, and in particular its representations that it has the ability to effectively conduct surveillance for the misuse of material non-public information despite permitting DMMs and others to use personal cellular telephones within telephone booths placed adjacent to the restricted Trading Floor, that the NYSE proposal is consistent with the Act.

Finally, the Exchange proposes amendments to the definition of "Trading Floor" in NYSE Rule 6A to reflect the renaming and relocation of certain trading areas.[42] The Commission believes that updating the names of the renamed or relocated trading areas in the Exchange rules to reflect the current use of the Exchange Trading Floor would eliminate any potential confusion among investors and other market participants on the Exchange regarding the parameters of the Trading Floor and thereby where certain conduct is, or is not, permitted.

Based on the foregoing, the Commission therefore finds the proposal to be consistent with the Act. The Commission believes that the proposal to exclude the area within the telephone booths described herein from the definition of Trading Floor, and thereby permit the use of personal communication devices within this area, while not without risk, is tempered by the existence of physical barriers that limit visual and auditory access between the telephone booths and the location of trading activities, the speed of electronic trading, and the fact that the Exchange retains jurisdiction over its members while they are in the telephone booths. The Commission expects that the Exchange will monitor compliance with Exchange rules within the telephone booths and on the Trading Floor and inform the Commission if it encounters difficulties in enforcing its rules or otherwise finds that the amendment to the definition of Trading Floor raises regulatory concerns.

---

[33] *See* Securities Exchange Act Release No. 60983 (November 10, 2009), 74 FR 59596, 59598 (November 18, 2009) (Order Approving SR–NYSE–2009–84) (noting that personal portable communications devices are not subject to the same surveillance as devices authorized and issued by the Exchange).

[34] The Commission notes that "[t]he term 'facility' when used with respect to an exchange includes its premises, tangible or intangible property whether on the premises or not, any right to the use of such premises or property or any service thereof for the purpose of effecting or reporting a transaction on an exchange (including, among other things, any systems of communication to or from the exchange, by ticker or otherwise, maintained by or with the consent of the exchange), and any right of the exchange to the use of any property or service." 15 U.S.C. 78c(a)(2).

[35] *See* Notice, *supra* note 3, at 39723. The Commission notes the Exchange's representation that "while inside the telephone booths, there is not any visual or auditory access to activities conducted at the trading posts or by Floor Brokers." *See id.*

[36] *See* note 32, *supra,* at 59597 n12, which noted when approving the use of personal portable or wireless communication devices outside the Exchange's Trading Floor that the majority of the doors that require card swipe entry are opaque. The Commission expects the Exchange to continue to ensure that the telephone booths remain in an area inside the Trading Floor turnstiles that minimizes any line of sight, including through the use of opaque glass on the booths. The Exchange has represented that it continues to monitor and surveil its Trading Floor for the misuse of material, non-public information, including trading ahead of customer orders, and that these surveillance procedures should be effective for monitoring for the misuse of material non-public information with the addition of telephone booths in close proximity to the Trading Floor within which individuals may use personal cellular telephones.

[37] *See* note 17 and accompanying text *supra.*

[38] *See* NYSE Rule 98(c)(3)(A).

[39] *See* NYSE Rule 98(c)(3)(C).

[40] *See supra* note 18, which noted that Floor-based non-public order information includes information expressed verbally.

[41] The Exchange has represented that in surveilling for compliance with its rules, NYSE can require a member firm to produce any additional information necessary regarding telephone booth use. In addition, the Exchange has represented that members firms will need to amend their policies and procedures concerning compliance with NYSE Rule 98 to account for the introduction of these telephone booths and will send an Information Memorandum to its members to remind them of this obligation, as well as obligations to comply with Rule 98 and, in particular, Rule 98(c)(3).

[42] *See* proposed Rule 6A.

IV. Conclusion

It is therefore ordered, pursuant to Section 19b(2) of the Act,[43] that the proposed rule change (SR–NYSE–2016–31) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[44]

Brent J. Fields,

Secretary.

[FR Doc. 2016–22730 Filed 9–20–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78851; File No. SR–FINRA–2016–036]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt NASD Interpretive Material 2210–2 as FINRA Rule 2211 (Communications With the Public About Variable Life Insurance and Variable Annuities) in the Consolidated FINRA Rulebook

September 15, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 31, 2016, Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a "non-controversial" rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to adopt NASD Interpretive Material 2210–2 (Communications with the Public About Variable Life Insurance and Variable Annuities) as FINRA Rule 2211 (Communications with the Public About Variable Life Insurance and Variable Annuities) in the consolidated FINRA rulebook without any substantive changes. FINRA also proposes to update cross-references within other FINRA rules accordingly.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org*, at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

As part of the process of developing a new consolidated rulebook ("Consolidated FINRA Rulebook"),[4] FINRA is proposing to transfer NASD Interpretive Material 2210–2 (Communications with the Public About Variable Life Insurance and Variable Annuities) ("NASD IM–2210–2") into the Consolidated FINRA Rulebook as FINRA Rule 2211 (Communications with the Public About Variable Life Insurance and Variable Annuities) without any substantive changes.

As with NASD IM–2210–2, proposed FINRA Rule 2211 provides a set of guidelines ("Guidelines") that must be considered—in addition to the standards governing communications with the public under FINRA Rule 2210 (Communications with the Public)—in preparing communications about variable life insurance and variable annuities.

NASD IM–2210–2 states that the Guidelines are applicable to "advertisements" and "sales literature" as defined in NASD Rule 2210, as well as "individualized communications such as personalized letters and computer generated illustrations, whether printed or made available on-screen." The proposed rule change makes technical changes to NASD IM–2210–2 by replacing references to "advertisements," "sales literature," and "individualized communications" with the current corresponding terms defined in FINRA Rule 2210. In adopting FINRA Rule 2210, FINRA updated the definitions under NASD Rule 2210 by adopting the defined terms "retail communication," for written communications that are distributed or made available to more than 25 retail investors within any 30 calendar-day period, and "correspondence" for written communications that are distributed or made available to 25 or fewer retail investors within any 30 calendar-day period."[5] Accordingly, the proposed rule change would replace references in NASD IM–2210–2, where applicable, to the terms (1) "advertisements" and "sales literature" with the term "retail communications,"[6] (2) "individualized communications" with the term "correspondence," and (3) "communications" with the term "retail communications and correspondence," as such terms are defined in FINRA Rule 2210. The proposed rule change also would amend paragraph (b)(5) of NASD IM–2210–2 by replacing the heading "sales literature and personalized illustrations" with "retail communications and correspondence," and by replacing the term "sales literature" in paragraph (b)(5)(B) with the term "retail communications and correspondence," to reflect the current intent and scope of this provision to include communications containing personalized illustrations that are sent to retail investors irrespective of whether a member distributes or makes them available to more than 25 retail investors within any 30 calendar-day period (qualifying the communication as a "retail communication") or 25 or fewer retail investors within any 30 calendar-day period (qualifying the communication as "correspondence").

---

[43] 15 U.S.C. 78s(b)(2).

[44] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] The current FINRA rulebook consists of: (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from New York Stock Exchange LLC ("NYSE") ("Incorporated NYSE Rules") (together, the NASD Rules and Incorporated NYSE Rules are referred to as the "Transitional Rulebook"). While the NASD Rules generally apply to all FINRA members, the Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE ("Dual Members"). The FINRA Rules apply to all FINRA members, unless such rules have a more limited application by their terms. For more information about the rulebook consolidation process, *see Information Notice,* March 12, 2008 (Rulebook Consolidation Process).

[5] *See* Securities Exchange Act Release No. 66681 (March 29, 2012), 77 FR 20452 (April 4, 2012) (Order Approving File No. SR–FINRA–2011–035). In addition, to the extent that a member distributed or made available a communication that qualified as an independently prepared reprint to more than 25 retail investors within a 30 calendar-day period, the communication also would fall under the definition of "retail communication."

[6] *See* Securities Exchange Act Release No. 64984 (July 28, 2011), 76 FR 46870 (August 3, 2011) (Notice of Filing File No. SR–FINRA–2011–035) (stating that communications that qualified as advertisements and sales literature generally would fall within the term "retail communication").

In addition, proposed FINRA Rule 2211 closely tracks the language of IM–2210–2 and makes only non-substantive, technical changes to the text of the NASD rule by, for instance, replacing the reference to a legacy NASD rule with the applicable FINRA rule.[7]

These proposed rule changes would correct references in IM–2210–2 for purposes of adopting it as a FINRA rule without changing the substantive meaning.

The proposed rule change also would replace all references to IM–2210–2 in FINRA Rules 0150 (Application of Rules to Exempted Securities Except Municipal Securities) and 9217 (Violations Appropriate for Disposition Under Plan Pursuant to SEA Rule 19d–1(c)(2)) with references to FINRA Rule 2211, accordingly.

FINRA has filed the proposed rule change for immediate effectiveness. The implementation date will be 30 days after the date of filing.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[8] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change, which does not substantively change the rule, is consistent with the Act because it is being undertaken pursuant to the rulebook consolidation process, which is designed to provide additional clarity and regulatory efficiency to FINRA members by consolidating the applicable NASD, Incorporated NYSE, and FINRA rules into one rule set.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As noted above, the proposed rule change will not substantively change either the text or application of the rule. FINRA would like to proceed with the rulebook consolidation process expeditiously, which it believes will provide additional clarity and regulatory efficiency to members.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received with respect to the proposed rule change to transfer IM–2210–2 into the Consolidated FINRA Rulebook without any substantive changes.[9]

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2016–036 on the subject line.

Paper Comments

- Send paper comments in triplicate to Robert W. Errett, Deputy Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2016–036. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2016–036 and should be submitted on or before October 12, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Brent J. Fields,

Secretary.

[FR Doc. 2016–22729 Filed 9–20–16; 8:45 am]

BILLING CODE 8011–01–P

---

[7] FINRA previously solicited comment on a proposal to move IM–2210–2 to the Consolidated FINRA Rulebook with substantive changes. *See Regulatory Notice* 08–39 (July 2008); *see also* Securities Exchange Act Release No. 61107 (December 3, 2009), 74 FR 65180 (December 9, 2009) (Notice of Filing File No. SR–FINRA–2009–070) (withdrawn on April 27, 2012). Given that FINRA would like to proceed with the rulebook consolidation process expeditiously to provide greater clarity and regulatory efficiency to FINRA members, FINRA is proposing to move IM–2210–2 to the Consolidated FINRA Rulebook without substantive changes at this time, but FINRA may consider proposing substantive changes to the rule as part of future rulemaking.

[8] 15 U.S.C. 78*o*–3(b)(6).

[9] *But see supra* note 7.

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 9728]

Bureau of Political-Military Affairs, Directorate of Defense Trade Controls: Notifications to the Congress of Proposed Commercial Export Licenses

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Department of State has forwarded the attached Notifications of Proposed Export Licenses to the Congress on the dates indicated on the attachments pursuant to sections 36(c) and 36(d), and in compliance with section 36(f), of the Arms Export Control Act.

DATES: *Effective Date:* As shown on each of the 36 letters.

FOR FURTHER INFORMATION CONTACT: Ms. Lisa V. Aguirre, Directorate of Defense Trade Controls, Department of State, telephone (202) 663–2830; email *DDTCResponseTeam@state.gov.* ATTN: Congressional Notification of Licenses.

SUPPLEMENTARY INFORMATION: Section 36(f) of the Arms Export Control Act (22 U.S.C. 2776) mandates that notifications to the Congress pursuant to sections 36(c) and 36(d) must be published in the **Federal Register** when they are transmitted to Congress or in a timely manner.

Following are such notifications to the Congress:

June 23, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of M400 carbines, 5.56 NATO, fully automatic, and accessories and technical data to Oman.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–137.

June 17, 2016

Honorable Paul Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearm parts and components abroad controlled under Category I of the United States Munitions List in amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of the M2A2 and M60E4 machine guns with components, barrels, spare parts and accessories to the Ministry of Defense of Tunisia.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–139.

June 23, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of M240/Mag58 machine guns, primary and spare barrel, and spare parts for the Kingdom of Saudi Arabia.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–141.

April 20, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of M240/Mag58 machine guns, primary and spare barrel, and accessories to the Government of Oman.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–143.

June 14, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles, including technical data, and defense services for the manufacture of significant military equipment abroad.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the Republic of Korea and the United Kingdom to support the design, development, manufacture, testing, and installation of the controllable pitch propeller and shafting system for the Republic of Korea Navy.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–144.

April 20, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) and (d) of the Arms Export Control Act, I am transmitting certification of a proposed license for the manufacture of significant military equipment abroad and the export of defense articles, including technical data, and defense services in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Germany to support the manufacture and assembly of semi-auto and full-auto pistols, rifles and carbines.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–145.

June 22, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a license for the export of defense articles, including technical data, and defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Egypt for the sale, modification, test, certification, maintenance, operation, training and post-delivery support of (12) AT–802U Border Patrol Aircraft configured with surveillance and weapons capability.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–072.

June 16, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts and components abroad controlled under Category I of the United States Munitions List in amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of various revolvers, semi-auto pistols, and bolt action rifles to Canada for commercial resale.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–097.

April 1, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of defense articles, including technical data, and defense services for the manufacture of significant military equipment abroad.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services, manufacturing know-how, and manufacturing assistance to manufacture, assemble, inspect, and deliver F135 engine parts and components in Turkey.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–099.

April 28, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) and (d) of the Arms Export Control Act, I am transmitting certification of a proposed license for the manufacture of significant military equipment abroad and the export of defense articles, including technical data, and defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Algeria to support the manufacture, procurement, testing, integration, operation, and maintenance of the Enhanced Position Location Reporting System (EPLRS) Extended Frequency-International (EPLRS–XF–I) and MicroLight-DH500 radio systems and associated ancillary equipment.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–105.

May 18, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of defense articles, including technical data, and defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Indonesia for the enhanced avionics and structural mid-life upgrade of F–16 Block 15 aircraft, including components, parts, accessories and support equipment.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–121.

June 17, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of defense articles, including technical data, defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data and defense services to perform depot level maintenance of F404–GE–400/402 engines installed on F–18A/B/C/D aircraft for end use by Australia, Canada, Finland, Kuwait, Malaysia, Switzerland and Spain.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–125.

June 17, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license amendment for the export of defense articles, including technical data, and defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Algeria, Canada, Denmark, India, Indonesia, Italy, Japan, Malaysia, Nigeria, Norway, Portugal, Qatar, the Republic of Korea, Saudi Arabia, Singapore, South Africa, Turkey, Turkmenistan, and the United Kingdom for the support of helicopter seating systems, restraint systems, cockpit airbag systems, floor armor, and associated components.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–126.

April 20, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of M240 machine guns to the Government of Oman.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–131.

June 15, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license amendment for the export of defense articles, including technical data, and defense services in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Turkey and Australia to facilitate integrated logistics for the Turkish 737 Airborne Early Warning and Control (AEW&C) Peace Eagle (PE) Integrated Logistics Support (ILS) Program.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–135.

June 14, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of machine guns, and spare parts package for the Sultanate of Oman.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–146.

May 16, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of M240 machine guns, primary and spare barrels, and spare parts for the Kingdom of Saudi Arabia.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 15–147.

April 20, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of barrel blanks to the Philippines for the manufacture of small arms.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–001.

June 14, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Sections 36(c) of the Arms Export Control Act, I am transmitting certification of a license for the export of defense articles, including technical data, and defense services in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Italy, Turkey, and the Netherlands for the manufacture of the F–35 Lightning II's Center Fuselage and related assemblies, subassemblies and components associated with all variants of the F–35 aircraft.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–002.

April 20, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of submachine guns to Panama.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–003.

June 22, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Sections 36(c) and 36(d) of the Arms Export Control Act, I am transmitting certification of a license for the manufacture of significant military equipment abroad and export of defense articles, including technical data, and defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to India to support the manufacture of 105mm and 155mm Howitzer Systems as well as spare parts packages.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–004.

April 29, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of 9mm semi-automatic pistols to France for end use by the government of France.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–005.

June 23, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Sections 36(c) and 36(d) of the Arms Export Control Act, I am transmitting certification of a proposed license for export for the manufacture of significant military equipment abroad and the export of defense articles, including technical data, or defense services abroad in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Algeria for the manufacture of the various RF Tactical Radio Systems and Accessories for end use by the Algerian Ministry of National Defense.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–007.

June 17, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license amendment for the export of defense articles, including technical data, and defense services in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the United Kingdom, Canada, and Singapore to support field tests for survivability and delivery of a modern armored personnel carrier.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–012.

June 24, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of 9mm and .45ACP semi-automatic pistols to Turkey.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–013.

May 26, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) and (d) of the Arms Export Control Act, I am transmitting certification of a proposed license for the manufacture of significant military equipment abroad and the export of defense articles, including technical data, and defense services in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the Republic of Korea to support the manufacture of ammunition and ammunition components.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–015.

April 29, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of 9mm and .357 caliber, semi-auto pistols, 9mm submachines, and 5.56 NATO carbines to Peru.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–016.

June 17, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of machine guns, rifles, sound suppressors and accessories to Colombia in support of counter-narcotics operations.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–018.

April 18, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of fully automatic rifles, grenade launchers, sound suppressors and accessories to the New Zealand Ministry of Defence.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–019.

June 23, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, certification of a proposed license for the export of defense articles, including technical data, and defense services in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to the Netherlands, Norway, Turkey, Italy and Japan for the manufacture of F–35 Aircraft Center Fuselage Components and Subassemblies.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–021.

April 28, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license amendment for the export of defense articles, including technical data, and defense services in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to France to support the integration, installation, operation, training, testing, maintenance, and repair of the Paveway II, Paveway III and Enhanced Paveway Weapon Systems.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–023.

May 16, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license amendment for the export of defense articles, including technical data, and defense services in the amount of $25,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Denmark to support the integration, installation, operation, training, testing, maintenance, and repair of the Small Diameter Bomb and Laser Small Diameter Bomb onto the F–16 aircraft.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–024.

June 17, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of defense articles, including technical data, and defense services in the amount of $100,000,000 or more.

The transaction contained in the attached certification involves the export of defense articles, including technical data, and defense services to Italy, Japan and Norway to support the manufacture of vertical tail control surfaces for the F–35 Lightning II Program.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–033.

June 17, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearm parts and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of various barrel blanks for bolt action rifles, various rifle barrels, receivers, and stocks; and accessories to Italy for commercial resale.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–035.

June 23, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of AR15 semi-automatic rifles and accessories to Canada for commercial resale.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–040.

June 23, 2016

Honorable Paul D. Ryan, Speaker of the House of Representatives.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting certification of a proposed license for the export of firearms, parts, and components abroad controlled under Category I of the United States Munitions List in the amount of $1,000,000 or more.

The transaction contained in the attached certification involves the export of M60E6 7.62mm general purpose machine guns, bolt breech assemblies and barrel blanks to Denmark.

The United States government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Julia Frifield,

Assistant Secretary Legislative Affairs.

Enclosure: Transmittal No. DDTC 16–045.

Dated: September 12, 2016.

Lisa V. Aguirre,

Managing Director, Directorate of Defense Trade Controls, U.S. Department of State.

[FR Doc. 2016–22763 Filed 9–20–16; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[AC 187–1K]

Schedule of Charges Outside the United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of availability.

SUMMARY: The Federal Aviation Administration (FAA) is announcing the availability of Advisory Circular (AC) 187–1K which transmits an updated schedule of charges for services of FAA Flight Standards Aviation Safety Inspectors outside the United States. The advisory circular has been updated in accordance with the procedures listed in 14 CFR part 187, Appendix A.

DATES: This AC is effective on October 1, 2016.

ADDRESSES: *How to obtain copies:* A copy of this publication may be downloaded from: *http://www.faa.gov/documentLibrary/media/Advisory_Circular/.pdf.*

FOR FURTHER INFORMATION CONTACT: Ms. Tish Thompkins, Flight Standards Service, AFS–50, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267–0996.

Issued in Washington, DC, on September 8, 2016.

John Barbagallo,

Deputy Director, Flight Standards Service.

[FR Doc. 2016–22776 Filed 9–20–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Office of Hazardous Materials Safety Meeting

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of public meeting.

SUMMARY: In preparation for the International Civil Aviation Organization's (ICAO) Dangerous Goods Panel (DGP) meeting to be held October 17–October 21, 2016, in Montreal, Canada, the Federal Aviation Administration's (FAA) Office of Hazardous Materials Safety and the Pipeline and Hazardous Materials Safety Administration's (PHMSA) Office of Hazardous Materials Safety announce a public meeting.

DATES: The public meeting will be held on Thursday, October 13, 2016 from 9 a.m. until 12 p.m.

ADDRESSES: The public meeting will be held at FAA Headquarters (FOB 10A), 2nd Floor, Bessie Coleman Conference Room, 800 Independence Avenue SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Questions regarding the meeting can be directed to Ms. Janet McLaughlin, Director, Office of Hazardous Materials Safety, ADG–1, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–9432, Email: *9-AWA-ASH-ADG-HazMat@faa.gov.* Questions in advance of the meeting for PHMSA can be directed to Mr. Shane Kelley, Assistant International Standards Coordinator, Pipeline and Hazardous Materials Safety Administration, PHH–10, 1200 New Jersey Ave. SE., Washington, DC 20590, telephone (202) 366–8553, Email: *shane.kelley@dot.gov.*

SUPPLEMENTARY INFORMATION: Participants are requested to register by using the following email address: *9-AWA-ASH-ADG-HazMat@faa.gov.* Please include your name, organization, email address, and indicate whether you will be attending in person or participating via conference call. Conference call connection information will be provided to those who register and indicate that they will participate via conference call.

We are committed to providing equal access to this meeting for all participants. If you need alternative formats or other reasonable accommodations, please call (202) 267–9432 or email *9-AWA-ASH-ADG-HazMat@faa.gov* with your request by close of business on September 27, 2016.

Information and viewpoints provided by stakeholders are requested as the United States delegation prepares for the International Civil Aviation Organization's Dangerous Goods Panel meeting to be held October 17–October 21, 2016, in Montreal, Canada.

Papers relevant to this ICAO DGP meeting can be viewed at the following Web page: *http://www.icao.int/safety/DangerousGoods/Pages/WG16.aspx.*

A panel of representatives from the FAA and PHMSA will be present. The meetings are intended to be informal, non-adversarial, and to facilitate the public comment process. No individual will be subject to questioning by any other participant. Government representatives on the panel may ask questions to clarify statements. Unless otherwise stated, any statement made during the meetings by a panel member should not be construed as an official position of the U.S. government.

The meeting will be open to all persons, subject to the capacity of the meeting room and phone lines available for those participating via conference call. Every effort will be made to accommodate all persons wishing to attend. The FAA and PHMSA will try to accommodate all speakers, subject to time constraints.

Issued in Washington, DC, on September 15, 2016.

Janet McLaughlin,

Director, Office of Hazardous Materials Safety.

[FR Doc. 2016–22795 Filed 9–20–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Passenger Facility Charge (PFC) Program; Draft FAA Order 5500.1B

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments, extension of comment period.

SUMMARY: FAA is extending the comment period on the draft FAA Order 5500.1B, Passenger Facility Charge published on August 5, 2016. This draft Order clarifies and updates statutory and regulatory requirements, including those affected by changes to the PFC statute from multiple FAA reauthorizations.

DATES: The comment period for the draft FAA Order 5500.1B published on August 5, 2016 is extended from September 30, 2016 to October 31, 2016.

ADDRESSES: An electronic copy of draft FAA Order 5500.1B is available through the Internet at the FAA Airports Web site at *http://www.faa.gov/airports/.* You may submit comments using the Draft PFC Order 5500.1B Comment Form available at the same web address, using any of the following methods:

- *Email: 9-faa-arp-pfc-order-55001b@faa.gov.*
- *Facsimile:* (202) 267–5302.
- *Mail:* FAA Office of Airports, Office of Airport Planning and Programming, Financial Analysis and PFC Branch (APP–510), Room 619E, 800 Independence Avenue SW., Washington, DC 20591.

For more information on the notice and comment process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Joe Hebert, Manager, Financial Analysis and Passenger Facility Charge Branch, APP–510, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267–8375; facsimile (202) 267–5302.

SUPPLEMENTARY INFORMATION: On August 5, 2016, the FAA published a notice titled "Notice and Request for Comments" (81 FR 51963). In that Notice, the FAA announced a request for comments on the draft FAA Order 5500.1B. The notice requested that interested parties submit written comments by September 30, 2016.

On August 19, 2016, three industry associations (Airlines for America, Airports Council International—North America, and the American Association of Airport Executives) submitted a joint request to extend the comment period by 30 days for several reasons. After careful consideration, the FAA has decided to extend the comment period for 31 days until October 31, 2016.

Issued in Washington, DC, on September 13, 2016.

Elliott Black,

Director, Office of Airport Planning and Programming.

[FR Doc. 2016–22721 Filed 9–20–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Availability of the Final Environmental Assessment (EA) and Finding of No Significant Impact/Record of Decision (FONSI/ROD) for the Runway 13/31 Shift/Extension and Associated Improvements Project for the Detroit Lakes-Becker County Airport (DTL) in Detroit Lakes, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA is issuing this notice to advise the public that the FAA has prepared and approved (August 23, 2016) a FONSI/ROD based on the Final EA for the DTL Runway 13/31 Shift/Extension and Associated Improvements Project. The Final EA was prepared in accordance with the National Environmental Policy Act (NEPA) of 1969, as amended, FAA Orders 1050.1F, "Environmental Impacts: Policies and Procedures" and 5050.4B, "NEPA Implementing Instructions for Airport Actions".

DATES: This notice is effective September 21, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Josh Fitzpatrick, Environmental Protection Specialist, FAA Dakota-

Minnesota Airports District Office (ADO), 6020 28th Avenue South, Suite 102, Minneapolis, Minnesota, 55450. Telephone number is (612) 253–4639. Copies of the FONSI/ROD and/or Final EA are available upon written request by contacting Mr. Josh Fitzpatrick through the contact information above.

SUPPLEMENTARY INFORMATION: The Final EA evaluated the DTL Runway 13/31 Shift/Extension and Associated Improvements Project. Due to airfield deficiencies identified by the FAA and Minnesota Department of Transportation (MnDOT) at DTL, the purpose of the proposed action is to provide a usable, reliable, and safe primary runway at an airport in or near the City of Detroit Lakes that is compliant with FAA and MnDOT design standards, guidance, and minimum system objectives for key airports.

The FAA and the City of Detroit Lakes jointly prepared the Final Federal EA/State of Minnesota Environmental Impact Statement (EIS), pursuant to the requirements of the NEPA and the Minnesota Environmental Policy Act.

The Final EA identified and evaluated all reasonable alternatives. Numerous alternatives were considered but eventually discarded for not meeting the purpose and need. Five alternatives (No Action, Alternative 3, Alternative 4, Alternative 5, and Alternative 7) were examined in detail. After careful analysis and consultation with various resource agencies, the City of Detroit Lakes selected Alternative 3 as the preferred alternative. Alternative 3 satisfies the purpose and need while minimizing impacts.

Alternative 3 includes a shift, widening, and extension to 5,200-feet of DTL's primary runway and parallel taxiway to meet FAA and MnDOT design standards and operator runway length requirements. The primary runway would be reconstructed to replace aging and deteriorating pavement. Two taxiways would be removed and replaced that connect the primary runway and parallel taxiway. An instrument approach to the Airport's primary runway with CAT–I minimums (½ statute mile visibility and 200-foot cloud ceiling height) to meet MnDOT requirements would be implemented. The Airport's Automated Weather Observing System (AWOS) will be relocated due to the project and property will be acquired to accommodate the runway and approach improvements. A relocation of the runway edge lights, runway end identifier lights (REILS), vertical approach slope indicator (VASI) unit, and a Medium Intensity Approach Lighting System with Runway Alignment Indicator Lights (MALSR) will be required. An access road for the MALSR will be required for maintenance activities.

Alternative 3 includes 15.5 acres of wetland impact. The loss of wetlands will be mitigated through the creation of 32.3 acres of wetlands onsite. An additional clearing of 17.6 acres of upland trees and 7.6 acres of wetland trees in the Runway 31 approach to provide adequate clearance of the applicable airspace will be required.

Based on the analysis in the Final EA, the FAA has determined that Alternative 3 will not result in significant impacts to resources identified in accordance with FAA Orders 1050.1F and 5054.4B. Therefore, an environmental impact statement will not be prepared.

Issued in Minneapolis, Minnesota on September 1, 2016.

Andy Peek,

Manager, Dakota-Minnesota Airports District Office, FAA, Great Lakes Region.

[FR Doc. 2016–22739 Filed 9–20–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Suffolk County, New York

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice to Rescind the Record of Decision and the Final Environmental Impact Statement (FEIS).

SUMMARY: The FHWA is issuing this notice to advise the public that the Record of Decision (ROD) and the Final Environmental Impact Statement (FEIS) for the proposed Interstate 495 (Long Island Expressway) Rest Area Upgrade Project between Exits 51 & 52 (eastbound) in the Town of Huntington, Suffolk County, New York (NYSDOT Project Identification Number: 0229.14) are being rescinded.

FOR FURTHER INFORMATION CONTACT: Peter Osborn, Division Administrator, Federal Highway Administration, New York Division, Leo W. O'Brien Federal Building, Suite 719, Clinton Avenue and North Pearl Street, Albany, New York 12207. Telephone (518) 431–4127

SUPPLEMENTARY INFORMATION: The FHWA, as the lead Federal agency, in cooperation with the New York State Department of Transportation (NYSDOT) signed a ROD on August 6, 2007, for the proposed Interstate 495 (Long Island Expressway) Rest Area Upgrade Project between Exits 51 & 52 (eastbound). The proposed project evaluated alternatives for upgrading the existing rest area for cars and trucks located on I–495/LIE eastbound between Exits 51 and 52.

Since the ROD was signed, NYSDOT notified FHWA that Federal funds will not be utilized during the final design and construction of the project. Therefore, FHWA has determined that the ROD and the Final Environmental Impact Statement dated May 21, 2007, will be rescinded since there will be no Federal action, and the requirements of the National Environmental Policy Act pursuant to 42 U.S.C. 4321, *et seq.* and 23 Code of Federal Regulations 771 no longer apply.

Comments and questions concerning the proposed action should be directed to FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 315; 23 CFR 771.123.

Issued on: September 12, 2016.

Peter Osborn,

Division Administrator, Federal Highway Administration, Albany, New York.

[FR Doc. 2016–22698 Filed 9–20–16; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0121; Notice 1]

Notice of Receipt of Petition for Decision that Nonconforming Model Year 2009 Jeep Compass Multipurpose Passenger Vehicles Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Receipt of petition.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that model year (MY) 2009 Jeep Compass multipurpose passenger vehicles (MPVs) that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards (FMVSS), are eligible for importation into the United States because they are substantially similar to vehicles that were originally manufactured for sale in the United

States and that were certified by their manufacturer as complying with the safety standards (the U.S.-certified version of the 2009 Jeep Compass MPVs) and they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is October 21, 2016.

ADDRESSES: Comments should refer to the docket and notice numbers above and be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

Instructions: Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

How to Read Comments submitted to the Docket: You may read the comments received by Docket Management at the address and times given above. You may also view the documents from the Internet at *https://www.regulations.gov.* Follow the online instructions for accessing the dockets. The docket ID number and title of this notice are shown at the heading of this document notice. Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically search the Docket for new material.

FOR FURTHER INFORMATION CONTACT: George Stevens, Office of Vehicle Safety Compliance, NHTSA (202–366–5308).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable FMVSS shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable FMVSS.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

G&K Automotive Conversion Inc. (G&K) of Santa Ana, California (Registered Importer R–90–007) has petitioned NHTSA to decide whether nonconforming 2009 Jeep Compass MPVs are eligible for importation into the United States. The vehicles which G&K believes are substantially similar are MY 2009 Jeep Compass MPVs sold in the United States and certified by their manufacturer as conforming to all applicable FMVSS.

The petitioner claims that it compared non-U.S. certified MY 2009 Jeep Compass MPVs to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most FMVSS.

G&K submitted information with its petition intended to demonstrate that non-U.S. certified MY 2009 Jeep Compass MPVs, as originally manufactured, conform to many applicable FMVSS in the same manner as their U.S.-certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that the non U.S.-certified MY 2009 Jeep Compass MPVs, as originally manufactured, conform to Standard Nos. 102 *Transmission Shift Lever Sequence, Starter Interlock, and Transmission Braking Effect,* 103 *Windshield Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 106 *Brake Hoses,* 113 *Hood Latch System,* 114 *Theft Protection,* 116 *Motor Vehicle Brake Fluids,* 118 *Power-Operated Window, Partition, and Roof panel System,* 124 *Accelerator Control Systems,* 135 *Light Vehicle Brake Systems,* 139 *New Pneumatic Radial Tires for Light Vehicles,* 201 *Occupant Protection in Interior Impact,* 202 *Head Restraints,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 206 *Door Locks and Door Retention Components,* 207 *Seating Systems,* 209 *Seat Belt Assemblies* 210 *Seat Belt Assembly Anchorages,* 212 *Windshield Mounting,* 214 *Side Impact Protection,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* 225 *Child Restraint Anchorage Systems* and 302 *Flammability of Interior Materials.*

The petitioner also contends that the subject non-U.S certified vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* replacement of the original instrument cluster with the U.S. model component and associated software, or modifying the existing speedometer such that speed is displayed in miles per hour (MPH) and the brake telltale displays the word "BRAKE" as described in the petition.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* installation of U.S.-conforming front side marker lamps, headlamps, and front side mounted reflex reflectors.

Standard No. 110 *Tire Selection and Rims:* installation of the required tire information placard.

Standard No. 111 *Rear Visibility:* inscription of the required warning statement on the face of the passenger mirror, or replacement of the passenger side mirror with the U.S.-model component.

Standard No. 138 *Tire Pressure Monitoring Systems:* installation of the original vehicle manufacturer's U.S.-model TPMS system including the module receiver, tire pressure sensors, associated software and additional components as necessary for a vehicle to conform to the standard.

Standard No. 208 *Occupant Crash Protection:* inspection of each vehicle and replacement of any non-conforming seatbelts and advanced air bag suppression system components with U.S.-model components as described in the petition as necessary for the vehicle to conform to the standard.

Standard No. 301 *Fuel System Integrity:* inspection of each vehicle and replacement of any non-U.S. model fuel system components with U.S.-model components as necessary to conform to the requirements of the standard as described in the petition.

The petitioner additionally states that a vehicle identification plate must be affixed to the vehicle near the left windshield pillar to meet the requirements of 49 CFR part 565.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above addresses both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A), (a)(1)(B), and (b)(1); 49 CFR 593.7; delegation of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2016–22720 Filed 9–20–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

September 16, 2016.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before October 21, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collections, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8117, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Control Number: 1545–1099.

Type of Review: Reinstatement of a previously approved collection.

Title: Form 8811, Information Return for Real Estate Mortgage Investment Conduits (REMICs) and Issuers of Collateralized Debt Obligations.

Form: Form 8811.

Abstract: A REMIC or issuer of a CDO (defined in Code of Federal Regulations section 1.6049–7(d)(2)) uses Form 8811 to provide the information required by 26 CFR 1.6049–7(b)(1)(ii) to be published in the directory of REMICs and issuers of CDOs, Pub. 938, Real Estate Mortgage Investment Conduits (REMICs) Reporting Information (And Other Collateralized Debt Obligations (CDOs)).

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 4,380.

OMB Control Number: 1545–1726.

Type of Review: Reinstatement of a previously approved collection.

Title: Practice Before the Internal Revenue Service.

Form: Forms 14360, 14364, 14392.

Abstract: Included in this collection are Form 14360, Continuing Education Provider Complaint Referral; Form 14364, Continuing Education Program Evaluation; Form 14392, Continuing Education Waiver Request; and Revenue Procedure 2012–12, describing procedures to be identified by the IRS as a qualifying organization accrediting continuing education providers.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1,777,125.

OMB Control Number: 1545–1738.

Type of Review: Extension of a currently approved collection.

Title: Revenue Procedure 2001–29, Leveraged Leases.

Abstract: Rev. Proc. 2001–29 sets forth the information and representations required to be furnished by taxpayers in requests for advance rulings on leveraged lease transactions within the meaning of Rev. Proc. 2001–28. The collection of information is required to establish the economic substance of the transaction and its *bona fides* as a true lease.

Affected Public: Individuals or households; Businesses or other for-profits.

Estimated Total Annual Burden Hours: 800.

OMB Control Number: 1545–1813.

Type of Review: Revision of a currently approved collection.

Title: Health Coverage Tax Credit (HCTC) Advance Payments (Form 1099–H).

Form: Form 1099–H.

Abstract: Internal Revenue Code, 26 U.S.C. 6050T, requires that providers of qualified health insurance coverage (defined in section 35(e)) that receive advance payments from the Department of the Treasury on behalf of eligible recipients pursuant to section 7527, must file Forms 1099–H, Health Coverage Tax Credit (HCTC) Advance Payments, to report those advance payments. They must also furnish a statement reporting that information to the eligible recipient.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 14,700.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–22759 Filed 9–20–16; 8:45 am]

BILLING CODE 4830–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Wednesday,
No. 183 September 21, 2016

Part II

Department of Health and Human Services

42 CFR Part 11
Clinical Trials Registration and Results Information Submission; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 11

[Docket Number NIH–2011–0003]

RIN 0925–AA55

Clinical Trials Registration and Results Information Submission

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule details the requirements for submitting registration and summary results information, including adverse event information, for specified clinical trials of drug products (including biological products) and device products and for pediatric postmarket surveillances of a device product to *ClinicalTrials.gov*, the clinical trial registry and results data bank operated by the National Library of Medicine (NLM) of the National Institutes of Health (NIH). This rule provides for the expanded registry and results data bank specified in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) to help patients find trials for which they might be eligible, enhance the design of clinical trials and prevent duplication of unsuccessful or unsafe trials, improve the evidence base that informs clinical care, increase the efficiency of drug and device development processes, improve clinical research practice, and build public trust in clinical research. The requirements apply to the responsible party (meaning the sponsor or designated principal investigator) for certain clinical trials of drug products (including biological products) and device products that are regulated by the Food and Drug Administration (FDA) and for pediatric postmarket surveillances of a device product that are ordered by FDA.

DATES: These regulations are effective on January 18, 2017. Additional information on the effective date and the compliance date can be found in Section IV.F.

FOR FURTHER INFORMATION CONTACT:

Regulatory Process: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, telephone (301–496–4607) (not a toll-free number), Fax (301–402–0169), or by email at *jm40z@nih.gov.*

Technical Information: Kevin Fain, Senior Advisor for Policy and Research, *ClinicalTrials.gov*, National Center for Biotechnology Information, NLM, NIH, Department of Health and Human Services, telephone (301–402–0650) (not a toll-free number), Fax 301–402–0118, or by email at *register@clinicaltrials.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of This Regulatory Action

This final rule clarifies and expands requirements for the submission of clinical trial registration and results information to the *ClinicalTrials.gov* database, which is operated by the NLM. It implements the provisions of section 402(j) of the Public Health Service Act (PHS Act) (42 United States Code (U.S.C.) 282(j)) as amended by Title VIII of FDAAA and including technical corrections made to FDAAA under Public Law 110–316), which were intended to improve public access to information about certain clinical trials of U.S. FDA-regulated drugs, biological products, and devices (also referred to as "FDA-regulated drugs, biological products, and devices" in this preamble) and certain pediatric postmarket surveillances of a device. Under section 402(j) of the PHS Act, those responsible for specified clinical trials of these FDA-regulated products have been required to submit registration information to *ClinicalTrials.gov* since December 26, 2007, summary results information for clinical trials of approved products as of September 27, 2008, and certain adverse events information since September 27, 2009. Section 402(j) of the PHS Act requires the Secretary of Health and Human Services to use rulemaking to expand the requirements for submission of summary results information, and authorizes the Secretary to use rulemaking to make other changes that enhance, but do not decrease, the available information about the specified trials.

This final rule does not impose requirements on the design or conduct of clinical trials or on the data that must be collected during clinical trials. Instead it specifies how data that were collected and analyzed in accordance with a clinical trial's protocol are submitted to *ClinicalTrials.gov.* No patient-specific data are required to be submitted by this rule or by the law this rule is intended to implement.

The major provisions of this rule are summarized below. More detailed discussions of these provisions are in Sections III and IV of this preamble.

Summary of the Major Provisions of the Regulatory Action

Applicable Clinical Trial

This final rule clarifies which clinical trials of FDA-regulated drug products (including biological products) and device products and which pediatric postmarket surveillances of a device product, are applicable clinical trials for which information must be submitted to *ClinicalTrials.gov.* The final rule considers all interventional clinical trials with one or more arms and with one or more pre-specified outcome measures to be controlled clinical trials. The final rule does not consider any expanded access use (*e.g.,* access under treatment INDs or treatment protocols, which provide widespread access, access for intermediate-sized patient populations, or access for individual patients) to be an applicable clinical trial. The final rule also describes an approach for evaluating, prior to registration, whether a particular clinical trial or study is an applicable clinical trial (see Section IV.A.5 and Section IV.B.2).

Responsible Party

This final rule specifies that there must be one (and only one) responsible party for purposes of submitting information about an applicable clinical trial. The sponsor of an applicable clinical trial will be considered the responsible party, unless and until the sponsor designates a qualified principal investigator as the responsible party. This final rule specifies the approach for determining who will be considered the sponsor of an applicable clinical trial under various conditions, what qualifies a principal investigator to be designated a responsible party by a sponsor, and how responsibility reverts to the sponsor if a designated principal investigator is unable to fulfill the requirements for submitting information to *ClinicalTrials.gov* unless and until the sponsor designates another principal investigator as the responsible party (see Section IV.A.2).

Registration

This final rule specifies requirements for registering applicable clinical trials at *ClinicalTrials.gov.* It requires that the responsible party register an applicable clinical trial not later than 21 calendar days after enrolling the first human subject (also referred to as participant or subject), and it specifies the data elements of clinical trial information that must be submitted at the time of registration. These data elements include the descriptive information, recruitment information, location and contact information, and administrative data elements listed in section 402(j) of the PHS Act, as well as additional required data elements under the Secretary's authority to modify the registration information requirements by rulemaking as long as such modifications improve, and do not reduce, the clinical trial information available to the public in *ClinicalTrials.gov.* We consider these additional required registration data elements necessary to enable the NIH to implement other statutory provisions, indicate the status of human subjects protection review of the trial, facilitate the public's ability to search and retrieve information from *ClinicalTrials.gov*, and help ensure that entries are meaningful and unambiguous. We note that some of these additional data elements required under this rule were included in *ClinicalTrials.gov* before FDAAA was enacted or have been implemented since 2007 as optional data elements (see Section IV.B).

Although section 402(j) of the PHS Act includes a provision delaying public posting of registration information for applicable clinical trials of unapproved or uncleared device products until the device product is approved or cleared, the final rule includes a provision under which the responsible party for an applicable device clinical trial can indicate to the Agency that it is authorizing the public posting of clinical trial registration information that would otherwise fall under the delayed posting provision prior to approval or clearance of the product (see Section IV.B.5).

Expanded Access Information

Section 402(j) of the PHS Act requires the submission of information regarding whether, for an applicable drug clinical trial of an unapproved drug product (including an unlicensed biological product), expanded access to the investigational product being studied in the applicable clinical trial is available under section 561 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). If the responsible party for an applicable clinical trial of an unapproved drug product (including an unlicensed biological product) is both the sponsor of the applicable clinical trial being registered and the manufacturer of the unapproved product, this rule requires the submission of a separate expanded access record containing details about how to obtain access to the investigational product. Once an expanded access record has been created for a particular investigational product and a National Clinical Trial (NCT) number has been assigned to it, the responsible party must update the applicable clinical trial(s) with that NCT number and provide that NCT number when submitting clinical trial registration information for any future applicable clinical trial(s) studying the same investigational product. The NCT number for the expanded access record allows *ClinicalTrials.gov* to link the existing expanded access record to the study record for the clinical trial (see Section IV.B.5 and Section IV.D.3).

Results Information Submission

This final rule addresses the statutory requirement for the submission of summary results information for applicable clinical trials of drug products (including biological products) and device products that are approved, licensed, or cleared by FDA. It also extends the requirement for results information submission to applicable clinical trials of drug products (including biological products) and device products that are not approved, licensed, or cleared by FDA. The rule requires the submission of data in a tabular format summarizing participant flow; demographic and baseline characteristics; primary and secondary outcomes, as well as results of any scientifically appropriate statistical tests; and adverse event information. In addition, the rule requires the submission of the full protocol and statistical analysis plan (if a separate document) (see Section III.D).

In general, this rule requires the submission of results information not later than 1 year after the completion date (referred to as the "primary completion date") of the clinical trial, which is defined as the date of final data collection for the primary outcome measure. Results information submission could be delayed for up to 2 additional years from the date of submission of a certification that either an unapproved, unlicensed, or uncleared product studied in the trial is still under development by the manufacturer or that approval will be sought within 1 year after the primary completion date of the trial for a new use of an approved, licensed, or cleared product that is being studied in the trial. This rule also permits responsible parties to request extensions to the results information submission deadlines for "good cause" as well as a permanent waiver of results information submission requirements for extraordinary circumstances (see Section IV.C.3 and Section IV.C.6).

Adverse Events Information

This final rule requires the responsible party to submit information summarizing the number and frequency of adverse events experienced by participants enrolled in a clinical trial, by arm or comparison group, as well as a brief description of each arm or group as a component of clinical trial results information. It also requires submission of three tables of adverse event information: One summarizing all serious adverse events; another one summarizing other adverse events that occurred with a frequency of 5 percent or more in any arm of the clinical trial; and finally, one summarizing all-cause mortality data by arm or group. This final rule clarifies that these adverse event tables must include information about events that occurred, regardless of whether or not they were anticipated or unanticipated. In addition, this rule requires responsible parties to provide the time frame for adverse event data collection and specify whether the collection approach for adverse events was systematic or non-systematic. The final rule does not require a responsible party to collect adverse event information that is not specified in the protocol (see Section IV.C.4).

Updates and Other Required Information

This final rule requires that all submitted information be updated at least annually if there are changes to report. More rapid updating is required for several data elements to help ensure that users of *ClinicalTrials.gov* have access to accurate, up-to-date information about important aspects of an applicable clinical trial or other clinical trial. The final rule also requires timely corrections to any errors discovered by the responsible party or the Agency during quality control review of submissions or after the information has been posted. The rule clarifies that the responsible party's obligation to submit updates and correction of errors ends on the date on which the required data elements for clinical trial results information have been submitted for all primary and secondary outcomes and all adverse events that were collected in accordance with the protocol, and the quality control review process has concluded (see Section IV.D.3).

Effective Date and Compliance Date

This final rule will be effective January 18, 2017. As of that date, the *ClinicalTrials.gov* system will allow responsible parties to comply with the rule. Responsible parties will have 90 calendar days after the effective date to come into compliance with the requirements of this rule (see Section IV.F).

Legal Consequences of Non-Compliance

This final rule outlines the potential civil or criminal actions, civil monetary penalty actions, and grant funding actions that may be taken if responsible parties fail to comply with the rule's requirements. It does not outline all potential legal consequences, *e.g.*, laws governing the veracity of information submitted to the federal government, however, and should not be understood as describing the exclusive means of enforcement that the government might undertake with respect to compliance with the provisions of section 402(j) of the PHS Act, including these regulations (see Section IV. E).

Costs and Benefits

Based on our cost estimates, this regulatory action is expected to result in $59.6 million in annual costs, and it is not expected to have a significant impact on the economy. The costs consist primarily of the time needed to organize, format, and submit to *ClinicalTrials.gov* information that was prepared for or collected during the clinical trial (*e.g.*, summary of key protocol details and clinical trial results information). The potential benefits include greater public access to information about ongoing and completed applicable clinical trials. Such information may help potential clinical trial participants to better understand their options for participating in new trials; to better enable funders and clinical researchers to determine the need for new trials; to provide more complete information for those who use evidence from clinical trials to inform medical and other decisions; and to better enable the scientific community to examine the overall state of clinical research as a basis for engaging in quality improvement (*e.g.*, with regard to research methods). The rule is also expected to provide greater clarity about what is required for those who are subject to the legal mandate to submit information to *ClinicalTrials.gov* (see Section V).

Commonly Used Abbreviations

ANDA	Abbreviated New Drug Application
API	Application Program Interface
BLA	Biologics License Application
CBER	Center for Biologics Evaluation and Research, FDA
CDER	Center for Drug Evaluation and Research, FDA
CDISC	Clinical Data Interchange Standards Consortium
CDRH	Center for Devices and Radiological Health, FDA
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
CSR	Clinical Study Report
CTRP	Clinical Trial Reporting Program, NCI
EMA	European Medicines Agency
EU	European Union
EudraCT	European Clinical Trials Database
FDA	Food and Drug Administration, HHS
FDAAA	Food and Drug Administration Amendments Act of 2007
FDAMA	Food and Drug Administration Modernization Act of 1997
FD&C Act	Federal Food, Drug, and Cosmetic Act
FOIA	Freedom of Information Act
FR	Federal Register
HDE	Humanitarian Device Exemption
HHS	Department of Health and Human Services
ICH	International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IOM	Institute of Medicine (now the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine)
IPD	Individual Participant Data
IRB	Institutional Review Board
IVD	In Vitro Diagnostic
LPLV	Last Patient Last Visit
MedDRA	Medical Dictionary for Regulatory Affairs
MeSH®	Medical Subject Headings
NCI	National Cancer Institute, NIH
NCT	National Clinical Trial
NDA	New Drug Application
NIH	National Institutes of Health, HHS
NLM	National Library of Medicine, NIH
NPRM	Notice of Proposed Rulemaking
OHRP	Office for Human Research Protections, HHS
PCORI	Patient-Centered Outcomes Research Institute
PDF	Portable Document Format
PHS Act	Public Health Service Act
PMA	Premarket Approval
PRS	Protocol Registration and Results System, *ClinicalTrials.gov*
RFA	Regulatory Flexibility Act
SAP	Statistical Analysis Plan
SNOMED CT®	Systematized Nomenclature of Medicine—Clinical Terms®
UMLS	Unified Medical Language System
U.S.	United States
U.S.C.	United States Code
U.S. TSA	U.S. Trade Secrets Act
UTSA	Uniform Trade Secrets Act, Uniform Law Commission
WHO	World Health Organization
XML	Extensible Markup Language

Table of Contents

I. Background
II. Overview of Statutory Provisions
III. Discussion of Public Comments on Selected Key Issues
  A. Scope and Applicability
  B. Submission of Results Information for Applicable Clinical Trials of Unapproved, Unlicensed, or Uncleared Products for Any Use
  C. Submission of Technical and Non-technical Summaries
  D. Submission of Protocols and Statistical Analysis Plans
IV. Discussion of Public Comments Related to Specific Provisions of the Regulations
  A. Subpart A—General Provisions
    1. What is the purpose of this part?—§ 11.2
    2. To whom does this part apply?—§ 11.4
    3. What are the requirements for the submission of truthful information?—§ 11.6
    4. In what format must clinical trial information be submitted?—§ 11.8
    5. What definitions apply to this part?—§ 11.10
  B. Subpart B—Registration
    1. Who must submit clinical trial registration information?—§ 11.20
    2. Which applicable clinical trials must be registered?—§ 11.22
    3. When must clinical trial registration information be submitted?—§ 11.24
    4. What constitutes clinical trial registration information?—§ 11.28
    5. By when will the NIH Director post clinical trial registration information submitted under § 11.28?—§ 11.35
  C. Subpart C—Results Information Submission
    1. Who must submit clinical trial results information?—§ 11.40
    2. For which applicable clinical trials must clinical trial results information be submitted?—§ 11.42
    3. When must clinical trial results information be submitted for applicable clinical trials subject to § 11.42?—§ 11.44
    4. What constitutes clinical trial results information?—§ 11.48
    5. By when will the NIH Director post clinical trial results information submitted under § 11.48?—§ 11.52
    6. What are the procedures for requesting and obtaining a waiver of the requirements clinical trial results information submission?—§ 11.54
  D. Subpart D—Additional Submissions of Clinical Trial Information
    1. What requirements apply to the voluntary submission of clinical trial information for clinical trials of FDA-regulated drug products (including biological products) and device products?—§ 11.60
    2. What requirements apply to applicable clinical trials for which submission of clinical trial information has been determined by the NIH Director to be necessary to protect the public health?—§ 11.62
    3. When must clinical trial information submitted to *ClinicalTrials.gov* be updated or corrected?—§ 11.64
  E. Subpart E—Potential Legal Consequences of Non-compliance
    1. What are potential legal consequences of not complying with the requirements of this part?—§ 11.66
  F. Effective Date, Compliance Date, and Applicability of Requirements in This Part
V. Regulatory Impact Statement
  A. Comments and Response
  B. The Final Rule
  C. Need for the Final Rule
  D. Benefits of the Final Rule
  E. Costs Associated With the Final Rule
    1. Registration of Applicable Clinical Trials
    2. Results Information Submission
    3. Delayed Submission of Results Information via Certification or Extension Request

4. Triggered Submission of Clinical Trial Information Following a Voluntary Submission
5. Expanded Access Records
6. Institutional Compliance Costs
F. Alternatives to the Final Rule
G. Regulatory Flexibility Act
H. Unfunded Mandates Reform Act of 1995
I. Federalism
VI. Paperwork Reduction Act of 1995
VII. Legal Authority
VIII. References
Regulatory Text

I. Background

This final rule implements requirements for submitting registration and summary results information for specified clinical trials of drug products (including biological products) and device products to *ClinicalTrials.gov*, the clinical trial registry and results data bank operated by the NLM, NIH, since 2000. This final rule provides for the expanded registry and results data bank specified in 402(j) of the PHS Act (42 U.S.C. 282(j)), as amended by Title VIII of FDAAA and including technical corrections made to FDAAA under Public Law 110–316. These provisions are intended to enhance patient enrollment, provide a mechanism to track subsequent progress of clinical trials, provide more complete results information, and enhance patient access to and understanding of the results of clinical trials (see 42 U.S.C. 282(j), section 402(j) of the PHS Act).

The requirements apply to the responsible party (the sponsor or designated principal investigator) for certain clinical trials of drug products (including biological products) and device products regulated by the FDA under designated sections of the FD&C Act.

The Notice of Proposed Rulemaking (NPRM) for Clinical Trials Registration and Results Submission was published on November 21, 2014, in the FR (79 FR 69566). We received nearly 900 comments during the 120 day public comment period, which closed on March 23, 2015. Of the total comments received, about 60 percent were nearly identical in content, expressing support for clinical trial transparency efforts and the goals of the NPRM and provided specific perspectives on a number of the proposals. Another large subset of comments also expressed support for clinical trial transparency and the NPRM goals, but did not comment on specific proposals. There were about 100 distinct comments that addressed specific NPRM proposals. As reflected below, all of the comments were reviewed and all points and perspectives were carefully considered. Section III includes discussion of comments on several key issues in the final rule, and Section IV includes discussion of comments related to each specific provision in the final rule. For each key issue and specific provision, we outline the statutory basis, the NPRM proposal, the relevant public comments, our response to the comments, and the approach taken in the final rule. The NPRM provided a comprehensive review of the legislative background and history that led to its development and, by extension, to this final rule. We review it again here in brief.

NLM initially developed the database, known as *ClinicalTrials.gov*, in response to the statutory mandate of section 113 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) to establish, maintain, and operate a data bank of information on certain clinical trials (these requirements currently are codified at 42 U.S.C. 282(i), PHS Act 402(i)), and in support of NLM's statutory mission to improve access to information to facilitate biomedical research and the public health (see 42 U.S.C. 286(a)). The registry became publicly available in February 2000. Since the establishment of *ClinicalTrials.gov*, the scientific community, general public, and others have called for many new measures to improve access to and transparency of information about clinical trials. In addition, various parties have developed and implemented trial registration policies including, for example, journal editors (through the International Committee of Medical Journal Editors (ICMJE)) [Ref. 1, 2] and industry (through the International Federation of Pharmaceutical Manufacturers and Associations) [Ref. 3]. *ClinicalTrials.gov* accepts information on trials other than those legally required to be registered in support of the mission of the NLM and other policies such as those from the ICMJE [Ref. 1, 2]. With the enactment of Title VIII of FDAAA, the legal mandate for *ClinicalTrials.gov* reporting was expanded to include more registration information for a broader set of clinical trials, as well as results information.

As discussed in the proposed rule, there are significant public health benefits to requiring the disclosure of the information required under this rule. Enhancements to the scope of *ClinicalTrials.gov* improve its utility in assisting individuals in finding trials for which they may be eligible to enroll, and then ensuring that their participation is honored and trust is enhanced by creating a public record of the trial and its results. In addition, access to more complete information about clinical trials has both scientific and other public health benefits. The scientific benefits relate to the prevention of incomplete and biased reporting of individual trials, and the provision of information about a more complete and unbiased set of trials; the resulting set of data about clinical trials can form a more robust basis for current medical decision making and future research planning. In addition, *ClinicalTrials.gov* provides an overview of the clinical trials enterprise, facilitating quality improvement in study focus, design, and reporting. The rule should also provide greater clarity about what is required for those who are subject to the legal mandate to submit information to *ClinicalTrials.gov*.

For many years, members of the scientific community, general public, industry, and others have been in active discussions about the need for increased access to information about clinical trials [Ref. 4]. Communities have expressed concern about the lack of publications from clinical trials [Ref. 5] (regardless of outcomes) and bias in the literature, [Ref. 6, 7] which may be due to selective reporting by trial sponsors or by journals in response to manuscripts that they deem less interesting. Interested parties have highlighted the importance of filling this gap because of missed opportunities to share knowledge that could have had implications for research participants who took part in these trials, future research participants who may benefit from this missing knowledge in the design of studies in which they will participate, and patients who may have benefited from the missing information in terms of a more robust understanding of their diseases, conditions, and potential treatments.

Even before this rulemaking, extensive research had been conducted using the clinical trial information that is publicly available on *ClinicalTrials.gov*. The published literature relying on *ClinicalTrials.gov* data includes:

- Studies characterizing the clinical research for specific conditions, such as acute kidney injury and the assessment of endpoints and sample size in prevention trials [Ref. 8];
- studies identifying research gaps in a domain, such as for pediatric studies [Ref. 9];
- studies assessing data mining methods, such as the systematic identification of pharmacogenomics information from clinical trials [Ref. 10];
- studies characterizing the overall clinical research landscape, such as the characteristics of clinical trials registered in *ClinicalTrials.gov* [Ref. 11];

- studies evaluating publication bias or selective reporting, such as the lack of publication for trials registered on *ClinicalTrials.gov* [Ref. 12];
- studies of research reporting, for example, by examining discrepancies between the *ClinicalTrials.gov* results database and peer-reviewed publications [Ref. 13]; and
- studies assessing specific research-related methods and issues, such as the reporting of non-inferiority trials in *ClinicalTrials.gov* [Ref. 14] and the use of *ClinicalTrials.gov* to estimate condition-specific nocebo effects and other factors affecting outcomes of analgesic trials [Ref. 15].

Many commenters identified the issues noted above, and supported the need for greater access to information about clinical trials. A large majority of comments in response to the NPRM expressed support for the rule, with many noting the value of transparency of clinical trials, in general. Commenters highlighted that accessible information about trials is critical for the public, including patients, and will contribute to better science in various ways. For example, one commented that the proposed rule promotes transparency, benefitting patients in the long run. Another asserted that doctors work with uncertainty and that access to all results information, regardless of statistical significance, can be important. Others argued that requiring more trials to be registered and reported will allow science to progress more quickly because scientists will be able to learn from trials that they otherwise would not have had access to, helping them to avoid "reinventing the wheel."

On the other hand, we recognize that the posting of results information from applicable clinical trials of unapproved, unlicensed, and uncleared products, as well as unapproved, unlicensed, or uncleared uses of approved/licensed/cleared medical products, presents special challenges. Despite the concerns raised by opponents to the rule (such as concerns from device manufacturers and the pharmaceutical industry about disclosure of what they view to be proprietary, confidential information and its impact on innovation and investment incentives, and concerns that the delay for submission of results information is insufficient given the length and cost of drug development), it is important that results information for each such clinical trial of an unapproved, unlicensed, and uncleared product be presented in an unbiased manner, but with the understanding that the evaluation of the overall benefit and risk profile of each such product, or each use of an already approved product, be determined by an assessment of the full evidence base for that product (*i.e.,* not from the results of any one trial in isolation). Under the FD&C Act, the PHS Act, and their implementing regulations, firms that market medical products are generally required to submit an application to FDA for premarket review, and provide robust scientific evidence that demonstrates that the product is safe and effective for each of its intended uses, before the firm distributes the product for each such use. During FDA premarket review of medical products, FDA also generally reviews proposed labeling for the intended use(s) of the product to ensure that the labeling provides adequate information for the safe and effective use of the product. Real harms have been associated with use of medical products for unapproved uses—harms to health as well as the diversion of resources to ineffective treatments [Ref. 16, 17].

A. Review of Scientific Benefits Related to Specific Provisions of the Rule

Registration Information

A public registry of trials enables interested parties, including patients, to find trials in which they might want to participate and facilitates the discovery of trials for academic research centers with experts studying particular diseases or conditions [Ref. 18]. The highly structured data, along with the search engine, enable members of the public to search for trials that might meet their needs by using a variety of technical and non-technical terms [Ref. 19]. This is of particular importance for trials that involve unapproved, uncleared, or unlicensed medical products that might not have a generic name [Ref. 20]. These trials tend to use company-specific code names that *ClinicalTrials.gov* links to their eventual generic name (if one is assigned). As a result, a user of the system can find all trials associated with a given product, even if they use different names (or codes) at different stages of the product development cycle. Without such a registry, there would be no single, centralized way to identify trials studying any intervention for any disease regardless of sponsor or funding for which an individual may be eligible (*e.g.,* previous Federal trial registries established under the Health Omnibus Extension of 1988 for trials for human immunodeficiency virus infection and acquired immune deficiency syndrome, commonly referred to as HIV/AIDS, and FDAMA 113 for effectiveness studies for serious or life-threatening diseases or conditions conducted under investigational new drug applications (INDs) were limited to certain conditions and one intervention type, *i.e.,* drugs).

The public record also ensures that each individual's participation in a trial is appropriately respected by preventing the conduct of "secret" trials, for which their existence is not publicly known (and/or their results are never publicly reported after completion or misreported—*i.e.,* reporting bias) [Ref. 21, 22]. The unique identifier assigned to each record (NCT number) also permits, for the first time, a way to identify each clinical trial unambiguously [Ref. 23] and link information about a single clinical trial from different resources/databases [Ref. 24].

The searchable, structured listing of trials also enables Institutional Review Boards (IRBs) [Ref. 25], researchers, funding agencies, systematic reviewers [Ref. 26, 27], and other groups, including the Presidential Commission for the Study of Bioethics Issues [Ref. 28], and the National Academies of Science workshops [Ref. 29], to see the landscape of trials on a given topic, by a particular funder, by geography [Ref. 30], by population [Ref. 9], or other relevant criteria. Providing these users with such a capability informs their judgments about the potential value of new trials, scientific and financial accountability of sponsors, as well as helping to ensure that assessments of the risks and benefits of a potential intervention for a particular use account for the totality of evidence from all prior trials. Such analyses of the clinical research also provide feedback and insights for the clinical research community itself, by informing the design and analysis of future trials [Ref. 11, 31, 32].

The information that describes the clinical trial in the registry records also facilitates assessments of the quality and appropriateness of trial reporting by enabling journal editors, researchers, and other readers of the medical literature to assess the degree to which the disclosed results (*e.g.,* journal articles, scientific conferences) accurately reflect the prespecified protocol and have accounted for all prespecified outcome measures. This helps to (1) prevent the type of incomplete results reporting that has been documented in conference and journal abstracts, as well as in full journal articles [Ref. 33] and (2) allow the members of the public to assess fidelity to the protocol, which is essential to understanding the validity of disclosed results [Ref. 34].

The freely downloadable registry data enable third parties to use the information that describes the clinical trial to meet other specific needs [Ref. 35], such as reformatting the data for constituents of various patient advocacy groups (*e.g.,* patients with breast cancer) [Ref. 36], data mining for associations among interventions and diseases studied worldwide, and for use in semi-automated data collection for conducting critical appraisals and systematic reviews to support evidence-based medicine. For example, while *ClinicalTrials.gov* does not itself match potential participants with relevant trials, the rule ensures the timely posting of registration information about trials currently enrolling participants. This information is used by third parties to provide matching services that help patients find trials that might be appropriate for them.

Summary Results Information

The public availability of results information helps investigators design trials and IRBs review proposed trials, by allowing them to weigh the proposed study's risks and benefits against a more complete evidence base than is currently available through the scientific literature [Ref. 37]. The rule facilitates better science through aiding in the identification of knowledge gaps for trials of all types of products, whether unapproved or approved and marketed. Mandatory submission and posting of results information will also help investigators avoid repeating trials on drug and device products (including biological products) that have been found to be unsafe or unsuccessful while also providing access to information that may help verify findings.

While the registry information at ClinicalTrials.gov can be used to determine where information might be missing from the literature (*e.g.,* missing trials, missing outcome measures) [Ref. 13, 38, 39], the results database fills many gaps in the medical evidence base by providing tabular objective data that summarize findings from trials. These data can be used by systematic reviewers and others who analyze the literature to develop evidence-based treatment and policy recommendations [Ref. 26].

FDAAA has led to the development of a minimum reporting set that provides key facts about the aggregate analyses for each trial without the accompanying narrative interpretations found in journal articles[Ref. 40]. In this way, results are made available in a timely manner for all prespecified primary and secondary outcome measures, and all serious and frequent adverse events, and complement the published literature [Ref. 41].

The submission and posting of results information on *ClinicalTrials.gov* may occur before, simultaneously with, or after journal publication, but is independent of journal submission and publication. The legal requirements help to fill substantial gaps in the database left by the non-publication (or very delayed publication) of a substantial portion of clinical trials in the medical literature [Ref. 42, 43]. In addition, the complete set of results information for all primary and secondary outcome measures that were specified in a study protocol supplements the more limited set of results data found in the published literature [Ref. 44]. The availability of results information from applicable clinical trials will help to prevent skewing of the evidence base that is the foundation of systematic reviews and clinical practice guidelines. In addition, if information were to be presented publicly about the safety profile of an approved drug product, the availability of clinical trial results information through ClinicalTrials.gov could help inform the public record about the drug product's safety [Ref. 45].

Review of Public Health Benefits Related to Specific Provisions of the Rule

Results information for trials of unapproved products may inform the assessment of risks and benefits that potential participants might face in subsequent studies of those same or similar products; they may also contribute to the overall assessments that are made of similar marketed products [Ref. 46]. Trials of products that are unapproved, unlicensed, and uncleared are unlikely to be published if the results of these trials are insufficient to support applications for product approvals (*e.g.,* because the study resulted in negative findings or was inadequately designed or executed). This rule's requirements that responsible parties submit results information from clinical trials of unapproved, uncleared, or unlicensed products regardless of whether approval, clearance, or licensure is sought, as well as the public posting of this information, are expected to alleviate the concerns regarding bias in the literature and selective publication. Frequently cited economic benefits of sharing clinical trial data generally include avoiding a suboptimal return on the financial resources invested by study funders and sponsors [Ref. 47], while the submission and posting of results information from trials of unapproved, uncleared, or unlicensed products in particular is expected to reduce costs by minimizing the number of redundant trials. Overall, the rule's requirement ensures the public availability and accessibility of information that likely would not otherwise have been in the public domain.

The reporting of an unambiguous accounting for all deaths, as required by the final rule, within each trial enables researchers and others to understand the most basic elements of the study in a way that was not previously possible in many cases [Ref. 48].

Mandatory submission and posting of the protocol and statistical analysis plan (SAP) for each reported trial provides a resource for researchers and others interested in understanding the detailed methods used to conduct a particular trial and analyze the collected data [Ref. 49, 50, 51]. Our reasoning behind their inclusion is more fully explained in Section III.D on Submission of Protocols and Statistical Analysis Plans, but we wish to emphasize that availability of the protocol and SAP is expected to provide users of *ClinicalTrials.gov* with a fuller picture of the trial. One of the aims of the statute and of the rule is to "provide more complete results information" (section 402(j)(3)(D)(i) of the PHS Act), which we believe complements the goals of increased transparency and accountability. As such, the addition of the protocol as clinical trial results information to be submitted and posted on *ClinicalTrials.gov* furthers this statutory purpose and significantly enhances the understanding of the trial and the context of the data fields and results information provided. It also enables readers to conduct a more complete evaluation of results [Ref. 47, 52, 53]. Although protocols are sometimes provided along with published articles, they are currently distributed among different journal Web sites and cannot be reliably found for most trials. Protocols also help to provide a more nuanced understanding of key trial methods, including, for example, the detailed eligibility criteria; how information was collected for key outcome measures and adverse events; and how data were handled, including detailed methods of statistical analyses. Such details of trial methods can affect the interpretation of a study's findings [Ref. 52, 53, 54, 55]. SAPs describe the analyses to be conducted and the statistical methods to be used, including "plans for analysis of baseline descriptive data and adherence to the intervention, prespecified primary and secondary outcomes, definitions of adverse and serious adverse events, and comparison of these outcomes across interventions for prespecified subgroups. The full SAP describes how each data element was analyzed, what specific statistical method was used for each analysis, and how adjustments were made for testing multiple variables. If some analysis methods require critical assumptions, data users will need to understand how those assumptions were verified.'' [Ref. 47].

Limiting *ClinicalTrials.gov* to Objective Data

As described in greater detail in Section III.C on Submission of Technical and Non-technical Summaries, the final rule does not require the submission of technical or non-technical narrative summaries of study results due to a lack of evidence that such summaries would always meet the statutory standard of not being misleading or promotional (section 402(j)(3)(D)(iii)(I) and section 402(j)(3)(D)(iii)(II) of the PHS Act). In fact, experts suggest that such summaries can lead to biased reporting, whether because of omission or commission [Ref. 56]. Presenting results information in a tabular format leads to a more objective database. We believe that actively avoiding the introduction of bias serves an important public health interest—one that Congress foresaw—and prevents *ClinicalTrials.gov* from being a platform in which data are conflated with opinions or interpretation.

In this regard, it should be noted that nothing in this rule authorizes a firm to use information posted in, or links to, other Web sites available on *ClinicalTrials.gov* to promote unapproved, unlicensed, or uncleared medical products or unapproved, unlicensed, or uncleared uses of approved or cleared medical products, or supersedes or alters other statutory and regulatory provisions related to such communications. For example, under the FD&C Act, the PHS Act, and their implementing regulations, firms that market medical products are generally required to submit an application to FDA for premarket review, and provide robust scientific evidence that demonstrates that the product is safe and effective for each of its intended uses, before the firm distributes the product for each such use. To the extent firms make a product available for one use (whether as a medical product or not), but make express or implied claims regarding the safety or efficacy of that product for another medical product use, for which it lacks the applicable approval, licensure or clearance, they are effectively evading the premarket review requirements of the applicable law and undermining the public health interests advanced by these requirements.

In addition, where emerging and developing scientific data are not yet sufficiently complete or robust to demonstrate safety and efficacy of the product for an initial or additional intended use, representations of safety and effectiveness can be misleading, particularly if addressed to health care providers and/or patients [Ref. 57, 58]. Marketing activities and communications can also be designed to persuade, promote, and influence prescribing and use in ways that are not based on valid scientific evidence, to the extent such evidence exists [Ref. 59, 60].

It is important to note that even though we are limiting the submissions to objective data elements, the government does not independently verify the scientific validity or relevance of the information submitted to *ClinicalTrials.gov* beyond the limited quality control review by NIH, which is focused on the clarity and completeness of the information submitted, not the quality, validity, meaning or relevance of the trial itself. Accordingly, the inclusion of data and information in the *ClinicalTrials.gov* platform, the links to other studies and Web sites, and the conduct of the limited quality control review by NIH, do not constitute a government affirmation or verification that the information within or referenced in the database, or communications that rely on that information, are truthful and non-misleading.

Other Benefits

Other benefits relate to the role in assisting individuals in finding trials in which to enroll, and then ensuring that their participation is honored and trust is enhanced by creating a public record of the trial and its results. It also fulfills an obligation to trial participants that is established between them and the research team. Individuals participate in clinical trials with the understanding that the research will contribute to the expansion of knowledge pertaining to human health. When trial information is withheld from public scrutiny and evaluation, the interpretation of the data and the public's trust in the research may be compromised. The rule helps to further the goal of ensuring that participation in research leads to accountability via the public reporting of information. Much has been written about the importance of trust in clinical research, and although many factors promote the development of trust, ensuring a public record of the trials in which people participate contributes significantly to this goal [Ref. 47, 61].

Finally, the availability of results information is expected to assist people in making more informed decisions about participating in a clinical trial by providing them and their care providers with access to information about the results of a broader set of clinical trials of various interventions that have been studied for a disease or condition of interest.

B. Anticipated Long-Term Benefits of ClinicalTrials.gov Beyond the Final Rule

ClinicalTrials.gov provides the scaffolding on which individual participant data (IPD (the next frontier in transparency) and other trial ''meta-data'' can be organized in the future. This is particularly important to catalyze the enormous potential value of data sharing. Such IPD (and, for example, associated biospecimens) are most valuable if their availability is identified in a searchable system and associated with key trial meta-data so that they can be used in a scientifically appropriate manner. *ClinicalTrials.gov* provides mechanisms for linking the trial records with sources of IPD and meta-data about each trial as recommended by the Institute of Medicine (IOM)in a 2015 report entitled Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risks and ICMJE [Ref. 47, 62]; the search interface allows for the easy identification of such data so that researchers can identify data for their secondary use.

II. Overview of Statutory Provisions

The final rule clarifies and establishes additional procedures and requirements for registering and submitting results information, including adverse event information, for certain clinical trials of drug products (including biological products) and device products, as well as for pediatric postmarket surveillances of a device product that are required by FDA under section 522 of the FD&C Act; the final rule requirements implement section 402(j) of the PHS Act.

Title VIII of FDAAA, enacted on September 27, 2007, section 801(a), amended the PHS Act by directing the Secretary of the Department of Health and Human Services (HHS), acting through the Director of the NIH (or the Agency) to expand the existing clinical trial registry data bank known as *ClinicalTrials.gov* and to ensure that the data bank is publicly available through the Internet. Among other duties, NIH is directed to expand the data bank to include registration information for a broader set of clinical trials than were required to register under FDAMA. Section 402(j) of the PHS Act specifies that identified entities or individuals, called responsible parties, are to submit registration information for certain applicable clinical trials of drugs (defined by section 402(j)(1)(A)(vii) of the PHS Act to include biological products) and devices, including any pediatric postmarket surveillance of a device required by FDA under section 522 of the FD&C Act (21 U.S.C. 360l). Section 402(j)(2)(A)(iii) of the PHS Act authorizes the Secretary of HHS to modify by regulation the data elements required for registration, provided that the Secretary provides a rationale for why such modification "improves and does not reduce" the information included in the data bank. The statute specifies certain deadlines by which registration information is to be submitted to the data bank.

Section 402(j)(3) of the PHS Act further directs the Agency to augment the registry data bank to include summary results information through a multistep process, as follows:

First, for those clinical trials that form the primary basis of an efficacy claim or are conducted after a product is approved, licensed, or cleared, the registry data bank is to be linked to selected existing results information available from the NIH and FDA (section 402(j)(3)(A) of the PHS Act). Such information includes citations to published journal articles focused on the results of applicable clinical trials, posted FDA summaries of FDA advisory committee meetings at which applicable clinical trials were considered, and posted FDA assessments of the results of any applicable drug clinical trials that were conducted under section 505A or 505B of the FD&C Act (21 U.S.C. 355a, 21 U.S.C. 355c).

Second, for each applicable clinical trial subject to section 402(j) of the PHS Act, the responsible party must submit to the data bank results information required under section 402(j)(3)(C) of the PHS Act. Such information is to include tables of demographic and baseline characteristics of the "patients who participated in the clinical trial" (section 402(j)(3)(C)(i) of the PHS Act), *i.e.,* the enrolled human subjects, and the primary and secondary outcome measures for each arm of the clinical trial, as well as a point of contact for scientific information about the clinical trial results and information on whether certain agreements exist between the sponsor and the principal investigator that limit the ability of the principal investigator to discuss or publish the results of an applicable clinical trial after it is completed. The *ClinicalTrials.gov* basic results component was launched on September 27, 2008.

In addition, section 402(j)(3)(I)(i) of the PHS Act directs the Secretary to issue regulations to "determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for applicable clinical trials (required to submit results information under section 402(j)(3)(C) of the PHS Act) in a manner and form that is useful and not misleading to patients, physicians, and scientists." If regulations are not issued by September 27, 2009, then section 402(j)(3)(I)(ii) of the PHS Act specifies that the statutorily mandated adverse event reporting provisions specified in section 402(j)(3)(I)(iii) of the PHS Act shall take effect, requiring the submission of certain information summarizing serious and frequent adverse events observed during an applicable clinical trial. Regulations were not issued by the deadline, so the statutorily mandated adverse event reporting provisions required by sections 402(j)(3)(I)(ii) and (iii) of the PHS Act took effect on September 27, 2009, at which time the *ClinicalTrials.gov* basic results database was updated accordingly. Section 402(j)(3)(I)(v) of the PHS Act indicates that adverse event information is "deemed to be" clinical trial information that is included in the data bank pursuant to the requirements for results information submission under section 402(j)(3)(C) of the PHS Act.

Third, section 402(j)(3)(D) of the PHS Act requires the Secretary to further expand the data bank by regulation "to provide more complete results information and to enhance patient access to and understanding of the results of clinical trials." It requires consideration of specific issues in developing the regulations, in particular:

(1) Whether to require submission of results information for applicable clinical trials of products that are not approved, licensed, or cleared (whether approval, licensure, or clearance was sought) (see section 402(j)(3)(D)(ii)(II) of the PHS Act.); and if submission of clinical trial results information is required for such applicable clinical trials, the date by which that information is required to be submitted. (See section 402(j)(3)(D)(iv)(III) of the PHS Act.);

(2) Whether non-technical written summaries of the clinical trial and its results can be included in the data bank without being misleading or promotional. (See section 402(j)(3)(D)(iii)(I) of the PHS Act.);

(3) Whether technical written summaries of the clinical trial and its results can be included in the data bank without being misleading or promotional. (See section 402(j)(3)(D)(iii)(II) of the PHS Act.);

(4) Whether to require submission of the full clinical trial protocol or only such information on the protocol as may be necessary to help evaluate the results of the trial. (See section 402(j)(3)(D)(iii)(III) of the PHS Act.);

(5) Whether the 1 year period for submission of results information should be increased to a period not to exceed 18 months. (See section 402(j)(3)(D)(iv)(I) of the PHS Act.); and

(6) Whether requirements for results information submission as set forth in the regulations should apply to applicable clinical trials for which results information required under section 402(j)(3)(C) of the PHS Act is submitted before the effective date of such regulations. (See section 402(j)(3)(D)(iv)(II) of the PHS Act.).

Section 402(j)(3)(D)(v) of the PHS Act further requires that the regulations shall establish:

(1) A standard format for the submission of clinical trial information. (See section 402(j)(3)(D)(v)(I) of the PHS Act.);

(2) Additional information on clinical trials and results written in nontechnical, understandable language for patients. (See section 402(j)(3)(D)(v)(II) of the PHS Act.);

(3) Procedures for quality control, with respect to completeness and content of clinical trial information, to help ensure that data elements are not false or misleading and are non-promotional. (See section 402(j)(3)(D)(v)(III) of the PHS Act.);

(4) Appropriate timing and requirements for updates of clinical trial information and whether and how such updates should be tracked. (See section 402(j)(3)(D)(v)(IV) of the PHS Act.);

(5) A statement to accompany the entry for an applicable clinical trial when primary and secondary outcome measures for such applicable clinical trial are submitted as a voluntary submissions after the date specified in section 402(j)(2)(C) of the PHS Act. (See section 402(j)(3)(D)(v)(V) of the PHS Act.); and

(6) Additions or modifications to the manner of reporting the data elements established under the results information submission provisions of section 402(j)(3)(C) of the PHS Act. (See section 402(j)(3)(D)(v)(VI) of the PHS Act.).

Section 402(j)(3)(D)(vii) of the PHS Act requires the Secretary to convene a public meeting to solicit input from interested parties on those issues. The public meeting was convened on April 20, 2009, on the NIH campus. The public meeting attracted more than 200 registered participants and 60 written comments. All of the comments received prior to, during, and after the public meeting are available in the Clinical Trials Public Meeting Docket, ID: NIH–2009–0002, at the *www.regulations.gov* Web site [Ref. 63]. We carefully reviewed the comments received in developing the proposed provisions to address the considerations enumerated in section 402(j)(3)(D) of the PHS Act. Many of the comments helped inform development of the proposed rule, which was issued on November 21, 2014, for public comment. For purposes of this rulemaking, we prepared a memorandum summarizing these comments from the public meeting and the issues commented upon [Ref. 64].

Furthermore, section 402(j)(4)(A) of the PHS Act directs that the data bank accept ''voluntary submissions'' of complete registration or complete results information for certain clinical trials for which such information would not otherwise be required to be submitted, provided that the responsible party complies with requirements that could involve submission of information on additional clinical trials.

Section 402(j)(5) of the PHS Act specifies certain procedures and penalties related to non-compliance. Among other things, it directs NIH to publicly post notices of noncompliance in the data bank; requires report forms under certain HHS grants to include a certification that required registration and results information submission under section 402(j) of the PHS Act are complete; requires federal agencies to verify compliance before future funding or continuation of funding under section 402(j) of the PHS Act; and grants FDA the authority to sanction responsible parties who fail to comply with section 402(j) of the PHS Act.

Section 801(b) of FDAAA includes certain conforming amendments to the FD&C Act, which make failure to comply with specified requirements of section 402(j) of the PHS Act, and the submission of false or misleading clinical trial information under section 402(j) of the PHS Act, prohibited acts under the FD&C Act (see 21 U.S.C. 331(jj)(1)–(3)). Committing any such prohibited act could subject the violator to criminal and/or civil penalties, including civil money penalties.

Section 801(c) of FDAAA requires the Secretary to issue guidance on how the requirements of section 402(j) of the PHS Act apply to a pediatric postmarket surveillance of a device, where that pediatric postmarket surveillance is not a clinical trial. The preamble of this final rule addresses this topic and is intended to serve as the required guidance.

Section 801(d) of FDAAA includes a preemption provision, which states that ''[u]pon the expansion of the registry and results data bank under section 402(j)(3)(D) of the PHS Act, as added by this section, no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.''

III. Discussion of Public Comments on Selected Key Issues

A. Scope and Applicability

The final rule covers requirements for the submission of clinical trial registration and results information to the *ClinicalTrials.gov* database. It includes expanded requirements for the submission of clinical trial registration and results information, as authorized by section 402(j) of the PHS Act, to improve public access to information about certain clinical trials of FDA-regulated drug products (including biological products) and device products. However, the rule does not impose requirements on the design or conduct of clinical trials or on the data that must be collected during clinical trials. Instead it specifies how data that were collected and analyzed in accordance with a clinical trial's protocol are to be submitted to *ClinicalTrials.gov.*

Following the public comment period, we received comments on a variety of the NPRM's sections and key issues, which are discussed in detail in the other subsections of Section III and in Section IV of this preamble. We also received comments from approximately 115 commenters on topics that, while important, are outside of the scope of the NPRM and the rule. Although we are not responding to these comments, the types of topics raised by these comments are described below.

We received comments suggesting that the rule should establish requirements for the conduct of clinical trials and that compliance with the rule should affect whether future clinical trials may proceed. For example, it was suggested that the rule should not permit trials with placebo groups to be conducted where there is no benefit to the participant and the condition studied is life-threatening. It was also suggested that studies should not be allowed to proceed to the next phase until all information submission requirements of the rule are met. We emphasize neither section 402(j) of the PHS Act nor this rule establishes requirements for clinical trial design or progress.

Commenters also provided input on the role of human subjects review boards, suggesting that the rule should require all proposed studies to be subject to their review, and that the rule should clarify HHS' position on human subjects protection. The role of human subjects review boards in the course of research is outside of the scope of this rule, but Human Subjects Protection Review Board Status is a required registration data element (see §§ 11.10(b)(35) and 11.28(a)(2)(iv)(D)).

Commenters also provided input on how they see the role of the rule with respect to FDA action. For example, it was suggested that the rule should prohibit the approval of a product application submitted to FDA unless results information submission requirements have been met. While the rule's results information submission requirements are connected to FDA approval, licensure, or clearance in terms of triggers for results information submission in certain cases, the rule does not affect, direct, or prohibit FDA from acting on a particular application or submission. Although FDA's actions with respect to approval, licensure, or clearance are outside the scope of this rule, FDA enforces FDAAA's registration and results information submission requirements and the requirement that a responsible party not submit false and/or misleading information. As described in more detail in Section IV.E, if FDA identifies a violation, the Agency may notify the responsible party and, as appropriate, initiate administrative proceedings for civil monetary penalties or the process for civil or criminal judicial actions.

We received comments about enforcement of the rule, suggesting that NIH and FDA should be enforcing the current requirements (*i.e.,* before the rule's effective date) as well as the additional results information reporting requirements in the final rule. We have addressed the applicability of the requirements of section 402(j) of the PHS Act and final rule throughout this preamble, including in the Effective Date, Compliance Date, and Applicability of Requirements in this Part discussion in Section IV.F. A few commenters suggested that FDA should enforce results information reporting requirements and that it should cancel marketing approvals "in cases of egregious misrepresentations." Commenters also proposed specific penalty structures, such as only penalizing the responsible party and not the institution and making all intentional violations criminal with mandatory prison sentences. They also proposed incentives, such as providing easier submission mechanisms and citable credit for shared data sets. The specifics of how and under what circumstances FDA will seek to enforce section 402(j) of the PHS Act are beyond the scope of the rule, as are issues relating to the marketing of FDA-regulated products. FDA may issue guidance regarding enforcement in the future. FDA enforces FDAAA's registration and results information submission requirements and the requirement that a responsible party not submit false and/or misleading information. As described in more detail in Section IV.E, if FDA identifies a violation, the Agency may may notify the responsible party and, as appropriate, initiate administrative proceedings for civil monetary penalties or the process for civil or criminal actions.

Although we did include in the preamble to the proposed rule a general discussion of the statutory procedures and penalties related to non-compliance (79 FR 69570), we did not otherwise discuss in detail the legal ramifications of failure to comply with the requirements of section 402(j) of the PHS Act, including these regulations. Other than the requirement that a responsible party not submit false or misleading information and the associated notice of potential liabilities for doing so (see § 11.6), the proposed codified text did not describe the potential legal consequences of failing to comply with the requirements of the rule. However, as discussed in Section IV. E below, we are adding a new § 11.66 that describes potential legal consequences provided for in the FDAAA enforcement provisions for failure to comply with the requirements in these regulations.

Some commenters suggested that the rule should require registered trials to make IPD datasets available to qualified researchers and some suggested that the rule should require the submission and disclosure of de-identified IPD datasets to *ClinicalTrials.gov*. The sharing or submission of de-identified IPD is not required or authorized in section 402(j) of the PHS Act, and is, thus, not included in this rule. In addition, *ClinicalTrials.gov* does not currently have a mechanism to directly collect datasets containing de-identified IPD. As discussed in Section I, however, *ClinicalTrials.gov* provides optional registration data elements that allow responsible parties to specify whether there is a plan to share the IPD or associated documents from the trial. Providing such meta-data about IPD in a searchable system facilitates identification of such data for use in a scientifically appropriate manner. In this way, we anticipate that *ClinicalTrials.gov* can be used in the future to catalyze IPD sharing.

Some commenters expressed concern about whether posting results information might be considered "prior publication" by journal editors thereby precluding subsequent publication of a journal article, while others suggested that posting of results information could be delayed an additional 12 months while papers undergo peer review. The rule implements the directives of section 402(j) of the PHS Act and is independent of the ICMJE clinical trial registration policy [Ref. 1, 2]. However, we note that the ICMJE has stated that submission of summary results to *ClinicalTrials.gov* will not be considered prior publication and will, thus, not interfere with journal publication [Ref. 2]. Interested parties are encouraged to explore the policies of the ICMJE and of the journals to which they seek to submit papers.

Some commenters also requested that NIH publish guidance clarifying the rule's requirements and provide training to clinical investigators about them. The Agency intends to continue making guidance documents and other materials available, including examples, case studies, and, as discussed below, a publicly-accessible checklist-based tool available at *https://prsinfo.clinicaltrials.gov* (or successor site) consisting of the relevant data elements and detailed explanation of each criterion. One commenter also suggested that one of the reasons for poor compliance with current law is the difficulty in interpretation and complexities around results reporting. We expect that the clarifications in this rule will help to address this concern.

Commenters provided suggestions regarding the usability of *ClinicalTrials.gov*. Comments regarding technical changes to the Web site are discussed in Section IV.A.4 ("In what format must clinical trial information be submitted?—§ 11.8"). While the details of the usability of *ClinicalTrials.gov* were not outlined in the NPRM or codified in this rule, we do wish to address these comments. Some commenters were dissatisfied with the process for entering data into the Protocol Registration and Results System (PRS), noting it is difficult to navigate, cumbersome, and complex. The PRS is the electronic system maintained by *ClinicalTrials.gov* that responsible parties use to register and submit results information for their studies, described at *https://prsinfo.clinicaltrials.gov*. They pointed to limitations of the PRS in sorting, filtering, and building queries, and some had specific suggestions on elements by which the site should be able to search, filter, and sort. We note that the PRS user interface has been updated incrementally over time with significant changes being made between 2014 and 2016, including the implementation of features to help streamline the results data entry process. In addition, based on usability study findings and expert evaluation, we further streamlined the data submission process for registration and results information, improved the reporting and portfolio management functions (with this series of enhancements, including one made in March 2016, addressing many of the concerns expressed by commenters), and provided enhanced resource materials for data submitters. We have also been providing 1-on-1 assistance to investigators submitting results in the PRS. While we continue our efforts to enhance the usability of the PRS and train personnel at academic institutions to provide centralized support to their investigators, the 1-on-1 assistance initiative has proven to be effective for providing customized support to investigators in fulfilling their requirements—especially for the many investigators who are using the PRS to submit results information for the first time. We will also expand the options in the PRS to accommodate the requirements of the final rule.

Commenters wanted the site to be user-friendly and allow for feedback, suggesting the NIH consult with experts to develop tools and with members of the public to ensure a user-friendly interface. We have conducted usability studies with a wide user audience and continue to obtain valuable feedback from a survey implemented on the public site. An example of a change that was made using this feedback was adding an option to search for trials based on the specific age of the potential participant (previously only age groups were easily searchable). We note that users may continue to provide feedback by using the "Contact NLM Help Desk" link on the bottom of every page on the *ClinicalTrials.gov* public Web site and by responding to the survey, when prompted. We intend to further consider this valuable input and collect additional input as we continue to refine the site and optimize it to support provider and patient needs and to improve its scientific utility. Our goal is for clinical researchers, data scientists, health care providers, patients, and the public users of the site to have a more positive experience and for the site to be functional for these diverse audiences.

Other commenters wanted to be sure the Agency has sufficient resources to carry out NLM's mission. Commenters also requested better communication between the *ClinicalTrials.gov* staff that operate the PRS and responsible parties, particularly via email, and suggested that the NIH reinstate in-person training sessions. Over the last year, we have expanded both the customer service and reviewer staff and provided comprehensive training to help ensure communications with responsible parties are as prompt, clear, and helpful as possible. We will continue to ensure staff are well-trained and monitor the satisfaction of responsible parties with the communications they receive. We will continue to offer PRS training to responsible parties. In addition, we will be launching a series of activities, such as webinars and presentations at selected conferences, to educate the biomedical research community about their obligations and to ensure that patients and care providers are aware of the information available at *ClinicalTrials.gov.* All such information will be available from *https://prsinfo.clinicaltrials.gov.* Overall, we are taking steps to improve the usability of the resource for all users of *ClinicalTrials.gov*, data submitters and data users alike.

Finally, a few commenters suggested that the law and the final rule should apply to all researchers conducting clinical trials with NIH funds. A number of commenters also took note of the proposed NIH Policy on Dissemination of NIH-Funded Clinical Trial Information, which was issued by NIH on November 19, 2014, in tandem with the publication of the NPRM [Ref. 65]. The policy proposed that all NIH-funded awardees and investigators conducting clinical trials should be expected to register their clinical trials and submit results information to *ClinicalTrials.gov.* NIH proposed that the policy would apply to awardees and investigators conducting clinical trials, funded in whole or in part by NIH, whether or not they are subject to section 402(j) of the PHS Act. The policy would, thereby, also apply to NIH-funded phase 1 clinical trials of FDA regulated drugs, small feasibility studies of devices, and trials of interventions not regulated by FDA, including surgical and behavioral interventions.

The draft policy proposed that the same registration and results information submission elements and reporting timeframes that would be required under the final rule would also apply to those clinical trials subject to the NIH policy, through the terms and conditions of the NIH funding awards. Most of the NPRM commenters who also commented on the draft NIH policy were supportive of it and of its application to a wider range of clinical trials [Ref. 66]. NIH considered those comments and comments received on the policy itself in developing the final policy. The final policy is substantively the same as the proposed draft policy in terms of scope, applicability, and the content and timing of registration and results information submission. It requires NIH-funded applicants and offerors to submit a plan for the dissemination of NIH-funded clinical trial information that will address how the policy's expectations for registration and results information submission will be met. NIH-funded awardees and investigators conducting clinical trials funded in whole or in part by NIH will be required to comply with all terms and conditions of award, including following their plan for the dissemination of NIH-funded clinical trial information. The final NIH policy, NIH Policy on Dissemination of NIH-Funded Clinical Trial Information, appears elsewhere in this FR [FR OFFICE, PLEASE CROSS–REFERENCE NIH POLICY] and includes a preamble discussing the public comments on the draft policy.

B. Submission of Results Information for Applicable Clinical Trials of Unapproved, Unlicensed, or Uncleared Products for Any Use

Overview of Proposal

Section 402(j) of the PHS Act requires the submission and posting of registration information and results information for applicable clinical trials of approved, licensed, or cleared products, as well as submission of registration information and posting requirements for applicable clinical trials of unapproved, unlicensed, or uncleared products. The statute provides the Secretary with the discretion through rulemaking to require the submission of results information from applicable clinical trials of products that are unapproved, unlicensed, or uncleared, whether or not approval, licensure, or clearance was sought. In particular, section 402(j)(3)(D)(ii)(II) of the PHS Act specifies that the Secretary, through regulation, shall establish whether results information should be required for "(aa) an applicable drug clinical trial for a drug that is not approved under section [505 of the FD&C Act] and not licensed under section [351 of the PHS Act] (whether approval or licensure was sought or not); and (bb) an applicable device clinical trial for a device that is not cleared under [section 510(k) of the FD&C Act] and not approved under section [515 or section 520(m) of the FD&C Act] (whether clearance or approval was sought or not)." Given this authority and various factors discussed in the NPRM (79 FR 69633), we proposed to require submission of results information from applicable clinical trials of FDA-regulated drugs (including biological products) and devices that are unapproved, unlicensed, or uncleared for any use as of the completion date, whether or not approval, licensure, or clearance was sought.

Regarding the scope of trials for which submission of results information in accordance with subpart C of the proposed rule is required, § 11.42(a) proposed to require submission of results information for all applicable clinical trials (*i.e.,* regardless of whether the product being studied was approved, licensed, or cleared) for which submission of registration information was required under proposed § 11.22 and for which the completion date was on or after the effective date of the rule. Section 11.42(b) proposed to require submission of results information for those applicable clinical trials for which submission of registration information was required under proposed § 11.22 and for which the completion date was before the effective date of the rule, but for which the relevant results information submission deadline in proposed § 11.44 was on or after the effective date of the rule and results information was submitted on or after the effective date, consistent with the applicable deadline established by proposed § 11.44.

With respect to the proposed results information submission deadlines for applicable clinical trials of drugs and devices that are not approved, licensed, or cleared by FDA for any use as of the completion date of the trial (where the completion date occurs prior to the effective date of the final rule), but are subsequently approved on or after the effective date, proposed § 11.44(a)(2) would require results information to be submitted by the earlier of (i) 1 year after the primary completion date or (ii) 30 calendar days after FDA approval, licensure, or clearance, except as otherwise provided under § 11.44(c), (d), or (e). Under proposed § 11.44(c), results information submission for applicable clinical trials studying FDA-regulated drugs (including biological products) or devices that were not approved, licensed, or cleared by the FDA for any use before the completion date of the trial may be delayed for up to 2 additional years (*i.e.,* up to 3 years after the primary completion date) if the responsible party certifies before the results information submission deadline that initial approval, licensure, or clearance of the studied product is being sought or may be sought by the sponsor at a future date. If the responsible party so certifies, all required clinical trial results information must be submitted by the earlier of (1) 30 calendar days after FDA approves, licenses, or clears the drug or device for any indication studied in the applicable clinical trial, (2) 30 calendar days after a marketing application or premarket notification is withdrawn and not resubmitted within 210 calendar days, or (3) 2 years from the date of certification (proposed § 11.44(c)(2)). Proposed § 11.44(d) addressed the submission requirements in situations where clinical trial results information has not been collected for a secondary outcome measure by the completion date.

The NPRM also addressed the situation in which results information for an applicable clinical trial of a device not previously approved or cleared is required to be submitted. Proposed § 11.35(b)(2) implemented section 402(j)(2)(D)(ii)(I) of the PHS Act, which prohibits the Director from posting submitted registration information prior to the date on which FDA approves or clears the device studied in the applicable clinical trial. Therefore, the timelines for submitting and posting clinical trial results information for applicable device clinical trials for unapproved or uncleared devices in proposed §§ 11.44 and 11.52, respectively, could result in the public availability of clinical trial results information for such trials before the information submitted during registration is posted in accordance with proposed § 11.35(b)(2) for these same trials, and for devices that are never approved or cleared, without such registration information ever being posted.

As we explained in the NPRM, posting clinical trial results information without sufficient corresponding public availability of certain descriptive information about the trial (that is similar to the type of information included as part of registration) would fail to provide the necessary context for understanding clinical trial results information, thereby significantly limiting understanding of posted results information (79 FR 69580). Section 402(j)(3)(D)(ii)(II) of the PHS Act authorizes the Secretary to require, through rulemaking, the submission of clinical trial results information for applicable clinical trials of products that have not been approved, licensed or cleared, whether or not approval, licensure or clearance had been sought. Specifically, it authorizes the Secretary to require, for an applicable device clinical trial of a device that has not been previously approved or cleared, the submission of the results information that is described in section 402(j)(3)(D)(iii) of the PHS Act. Section 402(j)(3)(D)(iii) of the PHS Act states that the regulations ''shall require, in addition to the elements described in [section 402(j)(3)(C) of the PHS Act] . . . [s]uch other categories as the Secretary determines appropriate.'' Thus, for applicable device clinical trials of unapproved or uncleared devices, the Secretary can require, through rulemaking, submission of ''such other categories'' of results information as the Secretary determines appropriate in addition to the information required under section 402(j)(3)(C) of the PHS Act. As discussed in the NPRM, in order to ''enhance patient access to and understanding of the results of clinical trials'' as required by section 402(j)(3)(D)(i) of the PHS Act, we interpreted ''such other categories'' of results information for applicable device clinical trials of unapproved or uncleared devices subject to proposed § 11.35(b)(2) and for which posting of registration information continues to be delayed to include, among other things, certain descriptive information that is similar to the type of information that is required to be submitted under section 402(j)(2)(A)(ii) of the PHS Act (79 FR 69581). Accordingly, proposed § 11.48(a)(6) required responsible parties for applicable device clinical trials of unapproved or uncleared devices, for which the device remained unapproved or uncleared at the time of results information submission to submit this descriptive information as part of clinical trial results information.

Comments and Response

A number of commenters addressed the topic of results information submission for applicable clinical trials of unapproved, unlicensed, or uncleared products. Commenters who supported the proposal stated that public availability of results information from trials of unapproved, unlicensed, and uncleared drugs (including biological products) and devices is expected to have public health benefits, as it helps protect the safety of participants who volunteer to be in clinical trials by reducing the likelihood that people will unknowingly design, approve, or participate in clinical trials that are duplicative and unnecessary (*e.g.,* because similar clinical trials have already been conducted but not published), or that are potentially ineffective or harmful (*e.g.,* because similar interventions have been shown to be harmful or ineffective in previous, unpublished clinical trials). Commenters also stated that results information from trials of unapproved, unlicensed, or uncleared products will reduce costs by minimizing the number of redundant trials.

Commenters expected that public availability of results information will assist potential human subjects in making more informed decisions about participating in a clinical trial by providing them and their care providers with information about the results of a broader set of clinical trials of various interventions that have been studied for a disease or condition of interest. Investigators and human subjects protection review boards that already have access to unpublished information from the sponsor of a clinical trial or the manufacturer of a drug or device will have access via *ClinicalTrials.gov* to information about other clinical trials of similar unapproved, unlicensed, or uncleared products that might help them in designing or considering the potential risks and benefits of participation in a clinical trial.

Commenters highlighted that results should be put to the broadest use because participants in research often put themselves at risk to participate and they deserve to have their participation contribute to the advancement of medical science, so that future patients may benefit from the knowledge gained. Commenters also indicated that increased transparency could help researchers learn from failed trials, verify findings, advance research, and improve overall understanding of disease. Commenters stated that trial results that are never published distort the evidence base for systematic reviews conducted to support development of clinical practice guidelines, which increases the time and effort needed to develop such guidelines. One commenter suggested that because it is common for products to be used outside of their approved marketing authorization in medical practice, information on trials of unapproved, unlicensed, or uncleared products should comply with robust reporting requirements in order to minimize potential risk to the public.

A couple of commenters mentioned that the requirement to submit results information from trials of unapproved products is consistent with the 2014 European Union (EU) clinical trial regulations. We agree with this point and note the ongoing regulatory efforts by the European Medicines Agency (EMA) to make results information from clinical trials of drugs conducted within the EU available in a publicly accessible data bank, regardless of the approval status of the drug [Ref. 67, 68, 69]. As discussed in the NPRM, all clinical trials of drugs performed within the EU are registered in EMA's European Clinical Trials Database (EudraCT) database, with information on phase 2, 3, and 4 clinical trials and all pediatric clinical trials made public through the EU Clinical Trials Register (79 FR 69578) [Ref. 70]. In October 2013, EMA released a new version of the EudraCT database to support the submission and public posting of summary clinical trial results on the EU Clinical Trials Register (EU CTR). The specified summary results information differs from the detailed information that would be submitted to EMA as part of a Marketing Authorization Application. As noted in the EMA's announcement, the EudraCT summary results data requirements are "substantially aligned" with those of the ClinicalTrials.gov results database [Ref. 71].

Commenters who were opposed to the proposal suggested that submission (and public posting) of results information for trials of products still under development may curtail incentives to invest in innovative research. Regarding devices in particular, it was suggested that requiring results information submission for trials of uncleared devices will have a negative effect on the development of new and innovative devices. Comments suggested that the risk of disclosing such results information would outweigh the benefit to the public, who cannot use a product that is not approved, licensed, or cleared. See the discussion of § 11.44 in Section IV.C.3 of this preamble for comments and the Agency response regarding the timeline for submission of results information for trials of unapproved, unlicensed, or uncleared products.

Several commenters raised legal challenges, citing the FD&C Act, the Freedom of Information Act (FOIA), and the U.S. Trade Secrets Act (U.S. TSA). We disagree with these comments. As an initial matter, we would like to clarify that FDA's disclosure laws and regulations do not apply to information submitted to *ClinicalTrials.gov*. FDA's statutory provisions apply to information obtained by the FDA pursuant to the enumerated statutory provisions of the FD&C Act, (see sections 301(j) and 520(c) of the FD&C Act) and FDA's general and product-specific disclosure regulations for drug products (including biological products) and device products apply to FDA records. (See 21 CFR part 20 and 21 CFR 312.120, 314.430, 807.95, 812.38, and 814.9). Information submitted to *ClinicalTrials.gov* is submitted to NIH pursuant to section 402(j) of the PHS Act and the regulations promulgated under it. Registration and results information submitted to *ClinicalTrials.gov* is not obtained pursuant to the FD&C Act, nor is it maintained as an FDA record.

With respect to the FOIA (5 U.S.C. 552), although the FOIA provides a general right to obtain information in Federal Agency records, it also establishes certain exemptions from disclosure; thus, while the FOIA is, broadly speaking, a disclosure statute, it also states that the disclosure requirements do not apply to information in Agency records if that information falls within one of the enumerated exemptions (see 5 U.S.C. 552(b)). In other words, an Agency is not required to release information under FOIA if that information falls within one of the enumerated exemptions. One of the categories of information that is exempted from disclosure is "trade secrets and commercial or financial information obtained from a person [that is] privileged and confidential." (5 U.S.C. 552(b)(4)). In contrast, the U.S. TSA (18 U.S.C. 1905) explicitly prohibits the release of such information by an Agency employee from Agency records. However, the U.S. TSA prohibitions do not apply when the disclosure of information is authorized by law. As established by the Supreme Court in *Chrysler Corp.* v. *Brown,* 441 U.S. 281 (1979), a statute or validly promulgated regulation requiring disclosure constitutes "authorization by law" for purposes of the U.S. TSA. Section 402(j) of the PHS Act requires that the Agency post certain registration and results information from applicable clinical trials, and further requires the Secretary to determine via rulemaking whether to require the submission and posting of results information from applicable clinical trials of unapproved, unlicensed, or uncleared drugs and devices (see section 402(j)(3)(D)(i) and (ii)(II) of the PHS Act), as well as to determine what results information must be submitted (see section 402(j)(3)(D)(iii)(IV) of the PHS Act). Accordingly, to the extent that clinical trial information, including but not limited to results information from applicable clinical trials of unapproved, unlicensed, or uncleared drugs and devices, described in section 402(j) of the PHS Act and this final rule may contain trade secret and/or confidential commercial information, the requirement that such information be posted on *ClinicalTrials.gov* is authorized by law for the purposes of the U.S. TSA.

It was also suggested that the provision in section 402(j)(2)(D)(ii)(I) of the PHS Act for delayed disclosure of registration information prohibits the posting of results information for applicable clinical trials of unapproved or uncleared devices. We believe the authority to require submission of results information for applicable clinical trials of unapproved and uncleared devices is clear from the language in section 402(j)(3)(D)(ii)(II)(bb) of the PHS Act. We have explained above the reasoning for requiring responsible parties to submit certain descriptive information as part of clinical trial results information for certain applicable device clinical trials of unapproved or uncleared device products, which is maintained in the final rule at § 11.48(a)(7).

One commenter also suggested that disclosure would be a forced release of trade secrets and confidential commercial information in violation of common law applicable to trade secrets. Another commenter raised a constitutional challenge, suggesting that the Agency would be disclosing trade secrets through this requirement, which they argued would constitute a regulatory taking of property without just compensation, in violation of the Fifth Amendment of the U.S. Constitution. We disagree.

The Supreme Court found in *Ruckelshaus* v. *Monsanto* (467 U.S. 986 (1984)) that trade secrets are property for purposes of the application of the Takings Clause of the Fifth Amendment. Most states have adopted the Uniform Trade Secrets Act (UTSA) and its definition of "protected trade secret interests": "[I]nformation, including a formula, pattern, compilation, program, device, method, technique, or process that: (i) Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." (See UTSA with 1985 Amendments § 1(4)).

However, even if there is a protected trade secret interest, the question of whether the government's proposed regulation amounts to a taking under the Fifth Amendment requires additional analysis. In *Penn Cent. Transp. Co.* v. *City of New York* (438 U.S. 104 (1978)), the Supreme Court set forth a three-factor analysis for determining whether a regulatory taking had occurred. Specifically, the Court identified (1) The extent to which an Agency's regulation interferes with distinct investment-backed expectations, (2) The economic impact of the regulation on the claimant, and (3) The character of the governmental action.

As an initial matter, none of the commenters identified any specific information that they assert constitutes trade secret information for purposes of a takings analysis, and that would be taken as a result of the statutory and regulatory requirements regarding submission to and posting on *ClinicalTrials.gov.* With respect to the factors outlined by the Supreme Court in *Penn Central,* we do not believe that drug and medical device manufacturers have a reasonable expectation at this time that the results information described in the final rule will be kept confidential. This is because (1) the field of drug and device development is highly regulated, (2) there has been robust public debate over the need for greater transparency of clinical trial results, and (3) it has been clear since the proposed rule was issued in 2014 (and in our view since the enactment of FDAAA, with its requirement that the rulemaking address the issue of results information submission and posting for applicable clinical trials of unapproved, unlicensed, and uncleared products), that such information can and may be made available to the public. None of the commenters have identified specific information required under the regulations that they believe would be of value to competitors, or that would allow competitors to benefit from innovators' scientific and technical advancements. Nor, as stated above, have they identified specific clinical trial results information that would be required to be submitted and that would meet the definition of a protected trade secret property interest for purposes of a takings analysis.

Regarding the final factor under *Penn Central,* we reiterate that, as discussed at length in this preamble, as well as in the proposed rule, there are significant public health benefits to requiring the disclosure of the information posted on *ClinicalTrials.gov,* including for applicable clinical trials of unapproved, unlicensed, and uncleared products. For many years the scientific community, general public, industry and others have engaged in high-profile public discussions about the need for increased access to information about clinical trials. Potential societal harms associated with having an incomplete medical evidence base have been reviewed; for example, studies have revealed that selective publication of clinical trial results could give a misleading picture about serious adverse effects of widely marketed drugs and about increased risks of such effects in certain segments of the population [Ref. 45].

As noted previously, the requirements for submission to and posting on *ClinicalTrials.gov* have the additional public health benefit of supporting international standards and norms (*e.g.,* Declaration of Helsinki, World Health Organization (WHO) Statement on Public Disclosure of Clinical Trials Results) and with industry, governmental, and other policies. The requirements under section 402(j) of the PHS Act, including those in this final rule, reflect our careful consideration and balancing of the burdens and benefits of the disclosure of this information for the drug and medical device industry and the public. These requirements further the important public health goals of enhancing patient enrollment in clinical trials, providing a mechanism to track the progress of clinical trials, and enhancing patient access to and understanding of the results of clinical trials.

The final rule maintains the proposal to require the submission of results information for applicable clinical trials of unapproved, unlicensed, or uncleared products, regardless of whether FDA approval, licensure, or clearance is or will be sought or obtained. We conclude that this requirement is in furtherance of the express statutory purpose of section 402(j)(3)(D)(i) of the PHS Act, which states that the Secretary shall expand the registry and results data bank "[t]o provide more complete results information and to enhance patient access to and understanding of the results of clinical trials." We considered a number of factors, notably the potential public health benefits of timely disclosure of results information for applicable clinical trials of unapproved, unlicensed, or uncleared products; the potential effects of disclosure on the competitive advantage of drug and device manufacturers, including incentives to invest in the development of new products intended to improve public health; and other results information submission requirements and policies (*e.g.,* those of the EMA). Other considerations include the relative burden on the responsible party of submitting results information for an applicable clinical trial of an unapproved, unlicensed, or uncleared product, the date by which results information must be submitted and practical issues of implementation and compliance.

As discussed in the NPRM (79 FR 69578), we recognize that the posting of results information about applicable clinical trials of unapproved, unlicensed, and uncleared products presents special challenges. Such information would be accessible to care providers and their patients but describe products that are not approved, licensed, or cleared, and thus may not be available outside of clinical trials. Further, even for approved, licensed, or cleared products, the posted results information might contain information about unapproved, unlicensed, or uncleared uses and further information may be helpful in understanding potential risks and benefits. We believe that the results information from any individual applicable clinical trial should be considered in the context of the broader set of information available about the product and alternative products. In keeping with current practice, we intend to establish links from clinical trial records in *ClinicalTrials.gov* to additional sources of information, including but not limited to the FDA and NIH information specified in section 402(j)(3)(A)(ii) of the PHS Act (we intend to indicate that the links were added by the Agency and not by the responsible party for the applicable clinical trial). We intend to provide information to assist users in better understanding and interpreting the information available in *ClinicalTrials.gov,* including materials that describe the general purpose and content of the data bank, a general description of the limitations of the results information presented, and cautions that the information should be used in conjunction with advice from healthcare professionals.

In this regard, it bears repeating that nothing in this rule authorizes a firm to use information posted in, or links to other Web sites available on, *ClinicalTrials.gov,* to promote unapproved, unlicensed, or uncleared medical products or unapproved, unlicensed, or uncleared uses of approved, licensed, or cleared medical products, or supersedes or alters other statutory and regulatory provisions related to such communications. In addition, the government does not independently verify the scientific validity or relevance of the information submitted to *ClinicalTrials.gov* beyond the limited quality control review by NIH. As discussed in Section III.C.12 of the NPRM, since responsible parties have been submitting results, the NIH has used a two-step process for quality control, starting with an automated system-based check prior to submission followed by a detailed, manual review after submission. This detailed review is based on quality review criteria for identifying apparent errors, deficiencies, or inconsistencies that are not detected by the automated checks. If any such problems are identified in the detailed, manual review, the proposed rule stated, the Director would send an electronic notification to the responsible party, indicating that the submission contains apparent errors, deficiencies, and/or inconsistencies listing such issues and requesting that they be addressed. Accordingly, the inclusion of data and information in the *ClinicalTrials.gov* platform, the links to other studies and Web sites, and the conduct of the limited quality control review by NIH, do not constitute a government affirmation or verification that the information within or referenced in the database, or communications that rely on that information, are truthful and non-misleading, particularly where they are being pointed to in the context of treatment decisions relating to the use of a product for an unapproved use.

The final rule does make a modification to the NPRM regarding applicable clinical trials that are completed before the effective date of the final rule and that study a product that is not approved, licensed, or cleared as of the effective date of the final rule. Proposed § 11.44(a)(2) would have required that for: (1) Applicable clinical trials that reach their completion date prior to the rule's effective date, (2) of products that are unapproved, unlicensed, or uncleared as of the completion date, and (3) for which the studied product is approved, licensed, or cleared by FDA on or after the effective date, if not otherwise subject to other deadlines specified in proposed § 11.44, results information must be submitted *by the earlier of* one year after the completion date or 30 calendar days after FDA approval, licensure, or clearance. A commenter suggested this could result in a situation in which a trial ends shortly before FDA approval or clearance and is not given a full year to submit results information after the trial's primary completion date. This provision has been removed from the final rule. As discussed in more detail below, an applicable clinical trial of an unapproved, unlicensed, or uncleared product that reaches its primary completion date before the effective date of the final rule is not subject either to the results information submission requirements in the final rule or the results information submission requirements specified in section 402(j)(3)(C) and section 402(j)(3)(I) of the PHS Act.

Commenters also suggested changes to the scope of the results information submission requirement for applicable clinical trials of unapproved, unlicensed, or uncleared products and addressed the statutory charge to the Secretary to determine whether the rule should require the submission of results information from applicable clinical trials of unapproved, unlicensed, or uncleared products, whether or not approval, licensure, or clearance will be sought (section 402(j)(3)(D)(ii)(II) of the PHS Act). Commenters suggested various options on the subject of the abandonment of product development, including that abandoned products should be identified, but submission of results information from applicable clinical trials of such products should not be required; commenters also suggested that the rule should only apply to applicable clinical trials of unapproved, unlicensed, or uncleared products that have been declared abandoned by the sponsor.

As explained in the proposed rule and above, while limiting results submission to those applicable clinical trials of unapproved, unlicensed, or uncleared products for which product development has been abandoned by industry would mitigate industry concerns about disclosing potentially valuable information to competitors, it would do little to address concerns about bias in the disclosure of information (79 FR 69577). Considerable information of potential scientific, clinical, and public significance would still be hidden from public view and would continue to be unavailable for consideration by human subjects protection review boards in assessing proposed clinical trials, by individuals considering participation in them, or by other researchers who are planning similar clinical trials or clinical trials of similar products. In addition, limiting results information submission and posting to applicable clinical trials of products for which product development has been abandoned would be difficult to administer because only the sponsor and/or manufacturer are in a position to determine that product development has been abandoned for all potential uses. Moreover, product development is often suspended for periods of time before being resumed when company priorities change or an investigational product is transferred to another company. Information about unapproved, unlicensed, or uncleared products for which product development may have been suspended might therefore remain undisclosed for long periods of time, depriving the public of the benefits that could result from disclosure.

A few commenters suggested that if the proposal is adopted, only a limited number of primary or key secondary outcomes prior to regulatory approval should be required to be submitted, or the final rule should allow the submission of redacted results information, especially when the product has not been approved, licensed, or cleared by FDA. The Agency disagrees; we believe that results information submission for all pre-specified primary and secondary outcomes, as required in the statute, is necessary to serve the public interest in having access to full and complete information. Selective reporting of results information would produce an incomplete and potentially skewed submission that ultimately would not serve the interests of the public and users of ClinicalTrials.gov.

Finally, it was suggested that device manufacturers be permitted to withhold proprietary information from the public as long as doing so does not pose a risk to patients. As discussed in Section IV.B. 5, trials of unapproved or uncleared device products qualify for a delay in the disclosure of registration information. However, based on the evidence available in the published literature as described in Section I of this preamble, we have concluded that selectively withholding of clinical trial information, including results information, at the discretion of the responsible party does not best serve the public interest. In addition, section 402(j) of the PHS Act requires the trial results in summary form (rather than individual participant-level form), which we believe can be provided without disclosing trade secret or confidential commercial information. Commenters did not indicate how such results information is or could be considered proprietary (or how it could contain proprietary information). Furthermore, even if the summary results information required to be submitted and posted does include such proprietary information, as discussed above, section 402(j) of the PHS Act and this final rule constitute authorization by law to disclose this information.

Final Rule

Based on the comments received and the statutory requirements, this final rule maintains the requirement to submit results information from applicable clinical trials of unapproved, unlicensed, and uncleared products consistent with the timelines outlined in § 11.44. The timely disclosure of results information, along with options for limited delays in results information submission deadlines with certification when seeking initial approval, licensure, or clearance, or approval, licensure, or clearance of a new use, takes into consideration the various interests at stake, including the public health benefits of disclosure and the commercial interests of sponsors.

Registration information must be submitted by the deadlines outlined in § 11.24, which do not distinguish between the submission of information from applicable clinical trials of approved, licensed, or cleared products and information from applicable clinical trials of unapproved, unlicensed, or uncleared products. Section 11.35 specifies (see Section IV.B.5) the timelines for posting of registration information for applicable drug clinical trials (regardless of product approval status), applicable clinical trials of device products that previously were approved or cleared, and applicable clinical trials of device products that have not been previously approved or cleared (which qualify for delayed posting in § 11.35(b)(2)(i)). Section IV.B.5 also describes new § 11.35(b)(2)(ii) that provides a process for a responsible party to indicate to the Director that it is authorizing the Director to publicly post its clinical trial registration information at ClinicalTrials.gov prior to the date of FDA approval or clearance of its device product. If the responsible party submits the Post Prior to U.S. FDA Approval or Clearance data element under § 11.28(a)(2)(i)(Q), the Director will post publicly the registration information that would otherwise be subject to delayed posting as specified in § 11.35(b)(2)(i), except for certain administrative data, as soon as practicable.

Under § 11.44, delayed submission of results information for applicable clinical trials involving products that are unapproved, unlicensed, or uncleared for any use is permitted only if the responsible party certifies as set forth in § 11.44 (c) (and prior to the standard results information submission deadlines as specified in § 11.44(a)) that the sponsor or manufacturer intends to continue with product development, meaning that it is either seeking, or may at a future date seek, initial approval, licensure, or clearance of the product under study in the applicable clinical trial. For the purposes of this final rule only, we interpret "use" to include "indication." For the purposes of this final rule, "indication" means "the disease or condition the product is intended to diagnose, treat, prevent, cure, or mitigate."

Section 402(j)(3)(D)(iv)(III) of the PHS Act directs that, in determining the timeline for submission of results information from applicable clinical trials of unapproved, unlicensed, or uncleared products, the Secretary take into account both the certification process under section 402(j)(3)(E)(iii) of the PHS Act "when approval, licensure, or clearance is sought" and "whether there should be a delay of submission when approval, licensure, or clearance will not be sought." Specifically with regard to applicable clinical trials of unapproved, unlicensed, or uncleared products for which approval, licensure, or clearance will not be sought, we interpret the phrase "will not be sought" in section 402(j)(3)D)(iv)(III)(bb) of the PHS Act to mean that the sponsor or manufacturer has no intention of continuing with commercial development of the product. For these trials, as with the disclosure of clinical trial results information from applicable clinical trials of all unapproved, unlicensed, or uncleared products, we believe that the public benefits of disclosure of results information outweigh any private, commercial interests (see discussion in Section II, Overview of Statutory Provisions). With respect to products for which initial approval, licensure, or clearance is, or may at a future date be sought, we recognize that, in many cases, this is information that will be known only to the sponsor or manufacturer of the drug product (including biological product) or device product and may not even be known to them at the time a clinical trial is completed, especially for an earlier stage trial, such as a phase 2 applicable drug clinical trial. Instead, the sponsor or manufacturer may know only that it intends to continue with product development, such as through the conduct of a subsequent clinical trial. Therefore, as a condition of delaying results information submission for unapproved, unlicensed, or uncleared products for any use, § 11.44(c) requires the responsible party to certify that the sponsor intends to continue with product development and either is seeking, or may at a future date, seek approval, licensure, or clearance. If the responsible party elects to submit a certification for delayed submission, it is the responsible party's obligation to verify that the particular applicable clinical trial meets the § 11.44(c) criteria, as explained in this preamble.

If, after submission of a certification under § 11.44(c), the drug product (including biological product) or device product studied in the applicable clinical trial becomes approved, licensed, or cleared for the use studied in the applicable clinical trial, results information will be due 30 calendar days after the date of product approval, licensure, or clearance. If, after submission of such a certification, initial approval is no longer being sought (*e.g.,* product development is abandoned), any continued delay in results information submission is not warranted, and the responsible party should submit results information as soon as practicable, but not later than 30 calendar days after the application or premarket notification is withdrawn without resubmission for no less than 210 calendar days (*i.e.,* 240 calendar days after submission of the withdrawal request). We limit the allowable delay period for results information submission for applicable clinical trials of unapproved, unlicensed, or uncleared products for any use to 2 years after the submission of a certification (*i.e.,* up to a total of 3 years after the primary completion date) for delayed results information submission, which parallels the statutorily-mandated 2 year limitation in § 11.44(b). The certification must be submitted prior to the date on which results information would otherwise be due under the standard submission deadline in § 11.44(a) (*i.e.,* 12 months after the primary completion date), and we permit only one certification to be submitted for each clinical trial.

In addition, the final rule maintains § 11.48(a)(6) as proposed in final § 11.48(a)(7), which requires responsible parties to submit additional descriptive results information for applicable device clinical trials of unapproved or uncleared devices for which registration information is not posted at the time of results information submission. In such situations, posting clinical trial results information with certain descriptive information that is similar to the type of information that is included as part of registration, provides the necessary context for understanding clinical trial results information and improves the understanding of posted results information. As explained in the proposed rule, facilitating this understanding is why journal articles and other reports of the results of clinical trials routinely include information about the disease or condition and interventions under study, the inclusion and exclusion criteria for participants, the location(s) of the trial, etc. Without such information, results data about patient demographics, outcomes, and adverse events could be uninterpretable and inaccessible. For example, patients and other users typically access clinical trial results by searching for (and retrieving) clinical trials with specific characteristics that involve a particular intervention or type of intervention, study a particular disease or condition, recruit certain types of subjects, take place during a particular time period, are conducted in a specific location or particular facility, are sponsored by a particular organization, or match a title or identification number they have found in other public sources.

Similarly, consistent with section 402(j)(3)(D)(i) of the PHS Act, providing information about the purpose of the study, its design, the intervention(s) studied, the types of subjects eligible to participate, the duration of the study, and the outcome measures will enhance the understanding of clinical trial results by researchers, healthcare providers, patients and other users of *ClinicalTrials.gov*. Users can benefit from knowing whether the clinical trial is completed, if data are still being collected for other outcome measures, or if the clinical trial was prematurely terminated. They can benefit from understanding whether information has been submitted for all anticipated outcome measures and corresponds to the outcome measures that the clinical trial was designed to achieve or whether the outcome measures changed during the course of the study. They can also benefit from information to assist in comparing results with the results of other clinical trials and with other publicly available information about a clinical trial of interest and other trials. Whether the clinical trial was reviewed for human subjects protection and who had authority over the conduct of the trial can also be useful. In addition, users may benefit from knowing who submitted the information and when it was last verified (*i.e.,* to indicate whether it might be out of date). Such information is not readily available from information submitted under § 11.48(a)(1)–(5), but is similar to the descriptive information provided during registration (*e.g.,* Primary Purpose, Primary Outcome Measure(s), Overall Recruitment Status) (see § 11.28(a)).

In addition, requiring responsible parties for applicable device clinical trials of unapproved, unlicensed, or uncleared device products to resubmit information submitted previously to the data bank during registration under § 11.28(a), in order to comply with § 11.48(a)(7), would be inefficient and impose an unnecessary burden on responsible parties. It would also introduce the possibility that the additional information provided at the time of results information submission would be inconsistent with the registration information and require the Agency to perform an additional quality review of the registration information. To promote efficiency, responsible parties must fulfill the requirement under § 11.48(a)(7) by affirming in the data bank when submitting clinical trial results information that they are submitting information that is already contained in the data bank and that such information has been updated as specified in § 11.64(a)(iii) and that it will be included as clinical trial results information. Once this affirmation is made, any information listed in § 11.48(a)(7) that was previously submitted to the data bank will automatically populate the results information data fields and be posted when results information is posted.

As discussed in Section IV.B.5 of this preamble, we also note that under final § 11.35(b)(2)(ii), a responsible party can indicate to the Director that it is authorizing the Director to publicly post its clinical trial registration information, that would otherwise be subject to delayed posting, as specified in § 11.35(b)(2)(i), prior to the date of FDA approval or clearance. For an applicable device clinical trial for which registration information described in § 11.28 has been posted in accordance with § 11.35(b)(2)(ii) before the submission of results information described in § 11.48, the requirement of § 11.48(a)(7) will not apply.

C. Submission of Technical and Non-technical Summaries

Overview of Proposal

Sections 402(j)(3)(D)(iii)(I) and (II) of the PHS Act specify that the regulations shall require "[a] summary of the clinical trial and its results that is written in non-technical, understandable language for patients" and "[a] summary . . . that is technical in nature," respectively, "if the Secretary determines that such types of summary [both non-technical and technical] can be included without being misleading or promotional." We interpreted this statutory condition to mean that such summaries should be required only if the summaries can be consistently produced by responsible parties in a way that is not misleading or promotional.

In the NPRM, we acknowledged that if non-technical and technical summaries could be consistently produced without being misleading or promotional, patients, members of the general public, clinicians, and researchers might benefit from brief, well-written, accurate, and objective summaries of the results of individual clinical trials (79 FR 69581). We discussed considerations related to the optimal format for narrative non-technical summaries and the question of whether a single, brief summary of an individual trial can provide sufficient background and context to avoid being potentially misleading to a clinician or patient interested in the clinical significance of the results. We described the challenges of producing summaries of trials with many outcome measures and adverse events without being selective. In addition to reviewing the relevant literature on the matter, we consulted with the FDA Risk Communication Advisory Committee [Ref. 72] and considered prior public comments from a public meeting held in 2009 [Ref. 63]. We indicated that, until further research could be conducted to assess the value of these summaries to the public and whether they can consistently be provided in a manner that is objective and not misleading, we would defer the decision about whether or not to require the submission of narrative summaries. We indicated that we would continue to provide links, where possible, from individual clinical trials in *ClinicalTrials.gov* to related peer reviewed literature and other information about the intervention, disease, or condition studied. The NPRM invited public comment pertaining to whether the inclusion of technical and non-technical summaries should be required in clinical trial data submission on *ClinicalTrials.gov* and what methodologies could be employed to ensure non-misleading, non-promotional, accurate, and consistent summaries (79 FR 69582).

Comments and Response

Comments addressed the question of whether the submission of technical and non-technical narrative results summaries should be required. Commenters noted that preparing both technical and non-technical summaries would be burdensome (*e.g.,* a commenter estimated that providing a non-technical summary would add 4 hours to the overall time to complete the submission of the results information for a clinical trial) and raised concerns regarding the ability of trial sponsors to write accurate, non-promotional, and non-misleading summaries. Commenters suggested that if results summaries were to be required, the Secretary would need to develop and issue guidelines or templates regarding their appropriate authorship, content, evaluation, and format to ensure consistency across summaries. No comments addressed the methods that might be employed to help answer the questions about whether narrative summaries could be consistently produced in a non-promotional and non-misleading manner. However, several commenters suggested external organizations with whom the Secretary might collaborate on narrative summary issues, namely the ICMJE to ensure that narrative summaries would not preclude future journal publications; the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard to investigate the format they are using for summaries; the FDA regarding Drug Trials Snapshots; and the Patient-Centered Outcomes Research Institute (PCORI) regarding peer review and public release of research findings. One commenter suggested that the summaries could be subject to a peer review process or prepared by independent medical writers. For both technical and non-technical summary results submission, there were commenters who supported deferral of a decision pending further exploration and the development of guidelines for preparing such documents.

With regard to technical summaries specifically, some commenters suggested that such summaries would be redundant to the required trial results information proposed in the NPRM. Other commenters expressed concerns regarding disclosure of proprietary information, particularly if such summaries were to be posted prior to FDA product approval. One commenter supported requiring technical summaries of results because they would suit the needs of professionals, manufacturers, and others in the industry. Several commenters suggested that as an alternative to technical summaries, *ClinicalTrials.gov* could systematically link to published reviews and/or clinical study reports (CSRs) submitted to FDA.

With regard to non-technical summaries specifically, commenters pointed out that it may be difficult for members of the public to understand study results provided in a technical summary and that the provision of lay summaries would enhance public understanding of the results. Others highlighted the difficulty inherent in writing a simple summary that presents the nuances of complex research findings, noting that systematic reviews, which synthesize all available evidence, are better sources of information for the lay public than brief summaries of a single trial. One commenter suggested that the informed consent document could be required in lieu of a lay summary because it provides important basic information in non-technical terms and has been reviewed by an independent party, *i.e.,* an IRB.

Taking the public comments into consideration, and given concerns about the potential for harm to public health from the promotion of medical products for unapproved uses, the Secretary is declining at this time to require narrative results summaries until further research is conducted to determine whether and, if so, how, summaries can be reliably and consistently produced without being promotional or misleading. Current approaches in the dissemination of trial summaries, such as FDA's Drug Trials Snapshots, PCORI's summary reports, and industry efforts to return summary results to participants, may be informative and will be reviewed and considered as part of any further research.

To provide additional information to the general public about a registered clinical trial, we will accept optional submission of the final version of the informed consent document to be posted on the associated record. Although the informed consent document does not provide information on interpreting the results of the trial, the document is written in lay language and its description of the trial's purpose, procedures, risks and potential benefits may help put the trial results into clearer context.

Final Rule

The final rule does not require the submission of technical or non-technical summaries of results to *ClinicalTrials.gov* because we have not identified evidence on the basis of which to conclude that there is a feasible way to ensure that the information contained in such summaries will be consistently produced without being misleading or promotional. We will continue to explore automated ways to consistently produce result summaries in a non-promotional, non-misleading way as well as mechanisms for linking results to information that might assist users in interpreting the results of clinical trials, such as systematic reviews and summary outcome information that sponsors and investigators provide to participants following the trial's completion. Should we determine in the future that narrative summaries can be consistently produced in a non-promotional, non-misleading way, a separate rulemaking process with notice and public comment will be undertaken.

D. Submission of Protocols and Statistical Analysis Plans

Overview of Proposal

Section 402(j)(3)(D)(iii)(III) of the PHS Act stipulates that regulations for an expanded registry and results data bank shall require at the time of results information submission, in addition to basic results information, the submission of "[t]he full protocol or such information on the protocol for the trial *as may be necessary* to help to evaluate the results of the trial" (emphasis added).

The NPRM noted that this statutory requirement could be satisfied in several ways, such as "(1) [r]equiring submission of additional structured data elements derived from, or describing, the protocol; (2) requiring submission of portions of the final protocol or other narrative information about the conduct of the study that is associated with the protocol (*e.g.,* a SAP, if not part of the protocol); or (3) requiring submission of the full protocol at the time of results submission, meaning the final version of the protocol, including all protocol amendments, in a format such as Portable Document Format (PDF)" (79 FR 69582). As we explained in the NPRM, given the proposals for submission of additional registration and results information, we did not propose to require submission of the protocol or other "information on the protocol." We did, however, solicit public comment on whether the registration and results information proposed for submission was sufficient to meet the statutory requirement. We asked for perspectives on the relative benefits and burdens of preparing and submitting any additional information and how such information would help evaluate the results of the clinical trial.

Comments and Response

Commenters supportive of a requirement for protocol submission maintained that it improves transparency and quality of reporting by providing information to the public about inclusion and exclusion criteria, the interventions studied, and trial outcomes. They suggested that the availability of the protocol allows users to compare reported outcomes and analyses against those pre-specified in the protocol. Some commenters asserted that a full understanding of the trial results is not possible without having access to the protocol and the trial's procedural details, details they stated permit the study to be replicated or built upon and that are pivotal to improving the design of future trials.

Some commenters pointed to an IOM recommendation that called for sharing of the protocol and SAP not only to help other investigators understand the original analysis, replicate or reproduce the study, and carry out additional analyses, but also because it complements trial registration in identifying trials that were initiated, allows future auditing of data sharing, facilitates meta-analyses and systematic reviews, promotes greater standardization of protocol elements (*e.g.,* interventions, outcomes), and may help reduce unnecessary duplication of studies [Ref. 47].

Another commenter maintained that an added benefit of making protocols available through *ClinicalTrials.gov* was that it would help journal editors, reviewers, and readers verify the a priori or post hoc nature of trial outcomes. They noted that journal editors encounter situations where outcomes reported in manuscripts do not match those listed on *ClinicalTrials.gov* and that posting of study protocols would be an important additional safeguard against reporting bias. Another commenter pointed out that a central archive for protocols would alleviate the burden on clinical trial investigators in addressing multiple requests for a copy of their protocols.

Commenters in support of a requirement for protocol submission also noted that, unless a standardized protocol format were required, the burden would be minimal because the document already exists. One commenter suggested that because the requirement is virtually burden-free and the benefits are so great, the requirement should be retroactive as far back as possible.

Commenters opposed to requiring protocol submission offered a number of reasons for this position. They suggested that the proposed registration and results elements provide sufficient information to understand the results of a clinical trial. Some thought the protocols should not be required because they will be confusing to the public and detrimental to recruitment, noting that they are technical, not standardized, and may have multiple amendments. Some asserted that protocols contain personally identifiable information, proprietary information, or other information that, if publicly disclosed, could be damaging to business interests. They suggested that a submission requirement would conflict with protections under the FD&C Act, FDA regulations, and FOIA. Commenters in support of protocol submission suggested redaction of such information was an appropriate remedy that should be allowed before submission. Finally, other commenters opposed redaction of information based on concerns it would be too burdensome and time consuming, with one commenter suggesting that allowing responsible parties to redact proprietary information might result in the exclusion of essential details needed for others to understand the results of the trial. No specific burden estimates associated with protocol redaction and submission were provided.

We appreciate that the data elements proposed in the NPRM are helpful to those reviewing and analyzing entries in *ClinicalTrials.gov,* and it was due to these additional elements that we did not propose the submission of the protocol in the NPRM. However, we found compelling and persuasive the arguments that protocols provide information in a context that is not captured by these elements alone and that the protocol will improve transparency and the quality of reporting by providing a more complete picture of the trial. We understand that although the registration data elements include descriptors of key features of the protocol, there are times when this additional detail may be helpful to researchers and others with an interest in the clinical trial's results and the ability to assess those results. For example, the protocol provides more detail than the registry and results data elements about methods of participant selection, randomization, masking, and assignment to arms; methods of collecting clinical trial data; specific information about clinical trial interventions (*e.g.,* other elements of care that were provided in addition to the specified interventions); and assessment of adverse events. The protocol may also contain information on the statistical techniques used to analyze collected results information, which helps others in interpreting the submitted results of a clinical trial. The protocol's description of the approach and circumstances that led to data collection may be helpful in contextualizing the submitted results information. We agree that this picture will help users of *ClinicalTrials.gov* to interpret the data elements that are required by this rule and that the protocol will be an important part of results information reporting for those wishing to fully understand the trial and its reported outcome measures.

We were also persuaded by the rationale for protocol submission discussed in the 2015 IOM report on sharing clinical trial data [Ref. 47], which described the value it would have for journal editors, reviewers, and readers in helping to verify trial outcomes and safeguard against reporting bias, and that it would help investigators in addressing multiple individual requests for a copy of their protocols. Further, it would allow for access to this information long after any prevailing document retention requirements have lapsed.

We did not find the argument that some might not understand the protocol to be a sufficient reason to not require its submission. Rather, although we acknowledge that there may be some individuals who may not understand the protocol, we believe that in general it will enhance understanding through its detail, content, and context. Regarding the suggestion that its posting could be detrimental to recruitment, we require the protocol at the time of results information submission, thereby eliminating the concern that posting the protocol will affect a trial's recruitment.

With regard to the argument that the protocol contains proprietary information, section 402(j)(3)(D)(iii)(III) of the PHS Act specifically requires the Agency to determine via this rulemaking whether to require the submission of the protocol. As discussed above in Section III.B, a statute or validly promulgated regulation requiring disclosure constitutes authorization by law to disclose information that might otherwise be considered to be trade secret and/or confidential commercial information as those terms are defined in the FOIA and the TSA. However, notwithstanding this authorization, if there is a case in which a responsible party believes that a protocol does contain trade secret and/or confidential commercial information, the responsible party may redact that information, so long as the redaction does not include any specific information that is otherwise required to be submitted under this rule. For example, the Intervention Name(s) for each intervention studied must be submitted under § 11.28(a)(2)(i)(J); therefore, this information may not be redacted from the protocol for that trial.

The burden of redacting protocols prior to submission is on the responsible party; the Agency does not intend to review protocols to assess whether they contain trade secret and/or confidential commercial information. Regarding the concern that redaction might result in a protocol lacking in essential details necessary to understand the results, we emphasize that responsible parties must comply with all other applicable results information submission requirements of this rule. The Agency may contact a responsible party if it appears that the responsible party has redacted information that is otherwise required to be submitted under these regulations. More specific guidance regarding redaction will be considered in the future.

In addition, we believe that concerns that might exist about a loss of competitive advantage are mitigated because the submission of the protocol is not required until after the trial is completed and clinical trial results information is submitted in accordance with the deadlines specified in § 11.44. We also note that § 11.44(c) provides for delays in submitting clinical trial results information for an applicable clinical trial that studies a product that is not yet approved by the FDA, thereby allowing for additional time before the protocol is required to be submitted.

Moreover, in our experience, protocols do not contain proprietary information or manufacturer details. However, as noted above, should there be a case in which a protocol does contain such information, redaction of such information will be allowed as long as the redaction does not encompass the information that is otherwise required to be submitted under this rule.

While some commenters were concerned about posting of personal information contained in protocols, in our experience, protocols generally do not contain information about individual clinical trial participants. However, if such information were to be included in a protocol, it should be redacted. Again, the burden of doing so is on the responsible party; the Agency does not intend to review protocols to assess whether they include personal information about trial participants. However, if it comes to the Agency's attention that personal information about trial participants has been included in a protocol, the Agency may contact the responsible party regarding the matter.

Protocols can include information about principal investigators and other individuals associated with conducting a clinical trial. In response to the concerns expressed by the commenters, responsible parties may redact personally identifying information about individuals who are involved in conducting the clinical trial if that information is not otherwise required to be submitted as part of clinical trial information. The Agency anticipates that because information such as work email addresses and contact information related to the clinical trial is likely available through other public sources (*e.g.,* a medical center's Web site), in many cases this information will not need to be redacted and, therefore, the burden associated with redaction will be minimal.

Because the protocol document already exists, we do not foresee this additional submission requirement to be burdensome. Rather, submission of the protocol itself is expected to be a minimally burdensome requirement that would involve an upload of an existing electronic document. We also expect that it will be less burdensome for a responsible party to submit the protocol than to extract and submit specified portions or selected information from a protocol. Similarly, as mentioned above, we do not expect redactions of any proprietary or personal information to be burdensome. The submission of the protocol at the time of the submission of clinical trial results information, rather than at the time of clinical trial registration information, also minimizes the burden on responsible parties in that any amendments that occurred over the course of the trial would already be incorporated into the document.

We also agree with the commenters who urged requiring submission of the SAP if it is not included in the protocol document. Many of the benefits of the protocol that were cited by commenters (summarized above) derived from the statistical analysis section of the protocol. If that section were written as a separate document (the SAP), then that document would be necessary to derive those same benefits (*e.g.,* better understanding of how data were collected and analyzed). As noted by commenters, the IOM recommended that both the full protocol and the SAP, including all versions and amendments, "should be shared to help other investigators understand the original analysis, replicate or reproduce the study, and carry out additional analysis" [Ref. 47]. SAPs describe the analyses to be conducted and the statistical methods to be used, including "plans for analysis of baseline descriptive data and adherence to the intervention, prespecified primary and secondary outcomes, definitions of adverse and serious adverse events, and comparison of these outcomes across interventions for prespecified subgroups. The full SAP describes how each data element was analyzed, what specific statistical method was used for each analysis, and how adjustments were made for testing multiple variables . . . if some analysis methods require critical assumptions, data users will need to understand how those assumptions were verified" [Ref. 47]. Some commenters objected to requiring the submission of both the protocol and the SAP, for the reasons described above; other commenters raised similar objections specifically with respect to the submission of SAPs. We find these objections unpersuasive for the reasons described above related to protocols. Therefore, we are requiring submission of the SAP as part of clinical trial results information.

If the SAP is submitted as part of the protocol, it need not be separately submitted. Some commenters objected to submission of SAPs because the SAPs might contain proprietary information. Although we think it unlikely that SAPs will contain proprietary information, we will accept redacted SAPs under the same terms as redacted protocols. We wish to emphasize that neither this requirement nor anything in this rule sets standards or creates requirements for the substantive content of protocols or SAPs.

Final Rule

The final rule requires submission of the full version of the protocol and the SAP (if a separate document) as part of clinical trial results information, as specified in § 11.48(a)(5). Submission of the protocol and SAP allows interested users of *ClinicalTrials.gov* to contextualize the reported clinical trial results information. We emphasize that this rule does not create requirements for the substantive content of protocols or SAPs. However, to allow for unambiguous identification of the submitted document(s), the protocol and SAP (if submitted as separate document) must contain a cover page that lists the Official Title (as defined in § 11.10(b)(2)), NCT number (as defined in § 11.10(a), if available), and the date of each document. We are requiring the inclusion of this additional information pursuant to our authority in section 402(j)(3)(D)(iii)(IV) of the PHS Act.

The requirements for submission of the protocol and the SAP are detailed in § 11.48(a)(5) of the final rule, which stipulates that "[a] copy of the protocol and the statistical analysis plan (if not included in the protocol), including all amendments approved by a human subjects protection review board (if applicable), before the time of submission under this subsection and that apply to all clinical trial Facility

Locations" must be submitted. It further indicates that "[t]he responsible party must include the Official Title (as defined in § 11.10(b)(2)), NCT number (as defined in § 11.10(a)) (if available), and date of the protocol and the statistical analysis plan on the cover page of each document." In addition, "[t]he responsible party may redact names, addresses, and other personally identifiable information, as well as any trade secret and/or confidential commercial information (as those terms are defined in the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905)) contained in the protocol or statistical analysis plan prior to submission, unless such information is otherwise required to be submitted under this part. The protocol and statistical analysis plan must be submitted in a common electronic document format specified at *https://prsinfo.clinicaltrials.gov.*"

The protocol and, if separate, the SAP, will be posted with other clinical trial results information, in accordance with § 11.52. If amendments are made to the protocol between the initial submission of partial clinical trial results information and later submission of additional partial results information, the responsible party must submit a copy of the revised protocol at the time of the later submission of partial results information, in accordance with § 11.44(d)(3)(i). However, the Protocol and Statistical Analysis Plan results data element in § 11.48(a)(5) are excluded from the updating requirements in § 11.64(a)(2)(i). Each submitted version of the protocol and SAP will continue to be available through the *ClinicalTrials.gov* archive site.

IV. Discussion of Public Comments Related to Specific Provisions of the Regulations

A. Subpart A—General Provisions

1. 11.2—What is the purpose of this part?

Overview of Proposal

The NPRM described in § 11.2 the overall purpose of the regulations. Implementing section 402(j) of the PHS Act (42 U.S.C. 282(j)), the rule provides the requirements and procedures for the submission of clinical trial information for certain applicable clinical trials and other clinical trials to the Director of the NIH to be made publicly available through *ClinicalTrials.gov.*

Comments and Response

As noted earlier, more than half of the submitted comments were identical in content. These commenters addressed proposed § 11.2 by recommending that the final rule be expanded to require registration and results information submission for all clinical trials. They reasoned that it was important and in the public interest for data on all clinical trials of drugs, biological products, and devices, and not only "certain applicable clinical trials," to be posted before the trial moves from one phase to the next. These commenters also suggested replacing the phrase "certain applicable clinical trials" in proposed § 11.2 with "all clinical trials."

The statute required the Agency to make a number of decisions through rulemaking, including whether to expand the requirement to report results information to applicable clinical trials of unapproved, unlicensed, or uncleared products, but it did not call for consideration of whether all clinical trials should be subject to registration and reporting requirements. Since the statute limits the applicability to applicable clinical trials as defined, these comments are outside the scope of the current rulemaking. Comments on the scope of the rule are further discussed in Section III.A of this preamble, Scope and Applicability, and in Section IV.B.2 in the discussion of § 11.22.

Final Rule

No changes are made in § 11.2 of the final rule.

2. 11.4—To whom does this part apply?

Overview of Proposal

Proposed § 11.4(a) specified that the regulations would apply to any person or entity that is considered to be the "responsible party," defined in section 402(j)(1)(A)(ix) of the PHS Act, for an applicable clinical trial that is required to be registered under § 11.22 or a clinical trial for which clinical trial information is submitted voluntarily under § 11.60. Proposed § 11.4(b), which would implement section 402(j)(1)(B) of the PHS Act, required the responsible party to communicate their identity and contact information to the Director by submitting the Responsible Party Contact Information data element during registration. Proposed § 11.4(c) outlined procedures for determining the responsible party for each applicable clinical trial or other clinical trial subject to this part. In particular, § 11.4(c)(1) specified who would be considered the sponsor and required that each applicable clinical trial or other clinical trial must have one sponsor. Furthermore, § 11.4(c)(2) established the requirements and procedures for a sponsor to designate a principal investigator to be the responsible party. If and when a designated principal investigator becomes unable to meet all of the requirements for being designated as a responsible party, proposed § 11.4(c)(3) outlined the mechanisms by which the sponsor would become the responsible party.

Comments and Response

Commenters suggested replacing the phrase "applicable clinical trial" in proposed § 11.4 with "all clinical trials." Commenters also expressed their opinions regarding proposed § 11.4 which focused on the designation of a responsible party. While commenters expressed support for assigning one responsible party per applicable clinical trial, they sought clarification regarding procedures for when a designated responsible party becomes unable to meet all of the requirements under § 11.4(c)(2)(i) (*e.g.,* principal investigator leaves the institution, principal investigator dies). Furthermore, a commenter suggested that the responsible party remain responsible for clinical trial information submission requirements even after leaving his/her institution and another suggested that the responsible party be able to change the sponsor, for example, when the principal investigator changes institutions.

As explained in the response to comments for § 11.2, section 402(j) of the PHS Act did not call for consideration of whether all clinical trials should be subject to registration and results information reporting requirements, and it limits the applicability to applicable clinical trials as defined. The Agency outlines in § 11.4(c)(2) and (3) of the final rule the procedures on the designation of a responsible party. These procedures specify that in the event a principal investigator who has been designated the responsible party no longer meets or is no longer able to meet all the requirements of § 11.4(c)(2)(i), the sponsor must withdraw the designation in the format specified at *https://prsinfo.clinicaltrials.gov* (or successor site), at which time the sponsor will be considered the responsible party unless and until the sponsor makes a new designation. These procedures, however, do not allow for a principal investigator who has been designated as the responsible party to change the sponsor because § 11.4(c) defines the sponsor as the default responsible party. Consistent with the statute, the sponsor is permitted to designate a principal investigator as the responsible party. However, if the designated principal investigator no longer meets or is no longer able to meet the criteria for being designated a responsible party (*e.g.*, due to changing institutions), the role of responsible party reverts back to the original sponsor.

Commenters also suggested that it would be more helpful if the electronic *ClinicalTrials.gov* system, *i.e.*, PRS, used by responsible parties to register and submit results information for their trials included a way for sponsors to designate a principal investigator as the responsible party. Commenters also suggested that PRS administrators should be allowed to control the settings in the Responsible Party field so they can set the "default" according to policies or preferences established by an institution.

Sponsors are not only responsible for assigning the role of responsible party, but they must also ensure that a designated principal investigator knows that he/she has been assigned the responsibility and has accepted the role and designation. Given the legal ramifications of the responsible party role, we do not believe it is appropriate for the assignment to be set through a default mechanism controlled through the PRS. We note that tools are available in the PRS to help remind responsible parties, including principal investigators designated as a responsible party, when a study record requires attention (see *https://prsinfo.clinicaltrials.gov* or successor site). We will continue to evaluate and develop tools in the PRS to help ensure that responsible parties understand their reporting obligations.

Final Rule

Final § 11.4 maintains the proposed approach of the NPRM, and clarifies in § 11.4(a) that the rule also applies to any responsible party required by the Director to register under § 11.62 to protect the public health (discussed in more detail in Section IV.D.2). Thus, final § 11.4(a) specifies that the rule applies to the responsible party for an applicable clinical trial that is required to be registered under § 11.22, for which clinical trial information is voluntarily submitted under § 11.60 (discussed in more detail in in Section IV.D.1), or for which the Director has determined, consistent with § 11.62, that clinical trial information must be submitted in order to protect the public health. The responsible party is either the sponsor of the clinical trial or a principal investigator who meets the criteria specified in § 11.4(c)(2) and has been so designated by the sponsor. In no case will this rule apply to the sponsor or principal investigator or other individual or entity associated with a clinical trial of drug or device not subject to FDA jurisdiction. Although section 402(j)(4)(A) of the PHS Act directs the Secretary to permit "[v]oluntary submissions" of clinical trial information for "a clinical trial that is not an applicable clinical trial or that is an applicable clinical trial that is not subject to" the registration provisions of section 402(j)(2) of the PHS Act, we interpret section 402(j) of the PHS Act and, thus, the final rule as not applying to anyone who submits information to *ClinicalTrials.gov* about trials of interventions that are not subject to FDA jurisdiction under sections 505, 510(k), 515, 520(m), or 522 of the FD&C Act, or section 351 of the PHS Act. Moreover, we interpret section 402(j) of the PHS Act as not applying to anyone who submits information to *ClinicalTrials.gov* for a study that is neither an applicable clinical trial (including a pediatric postmarket surveillance of a device product as defined in this part) nor a clinical trial as defined in § 11.10(a), even if it involves a drug or device subject to sections 505, 510(k), 515, 520(m), or 522 of the FD&C Act, or section 351 of the PHS Act. For example, section 402(j) of the PHS Act would not apply to information submitted for a study using a diagnostic tool that is a device product subject to section 510(k) of the FD&C Act, such as a magnetic resonance imaging scanner, that is not studying the device product and is not otherwise an applicable clinical trial, clinical trial as defined in § 11.10(a), or pediatric postmarket surveillance of a device product as defined in this part. (See the discussion of "Studies a U.S. FDA-regulated Device Product" in Section IV.B.4) Consistent with other statutory authorities of the Agency and long-standing practice, however, *ClinicalTrials.gov* may, and does, accept registration and results information on clinical studies, as defined in § 11.10(a), that are not subject to the requirements of section 402(j) of the PHS Act (including under this rule).

Section 11.4(b) of the final rule implements section 402(j)(1)(B) of the PHS Act, which provides that the Secretary "shall develop a mechanism by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial [registration] information." Section 11.4(b) provides that the responsible party's identity and contact information must be included as part of the clinical trial information that is submitted in accordance with § 11.28(a)(2)(iii)(B) and § 11.28(a)(2)(iv)(F) and updated in accordance with § 11.64(a). Responsible party contact information must be provided under the data element entitled Responsible Party Contact Information (§ 11.28(a)(2)(iv)(F)) that, as specified in § 11.10(b)(37) includes the name, official title, organizational affiliation, physical address (*i.e.*, street address), mailing address, phone number, and email address of the responsible party or of a designated employee of the organization that is the responsible party.

Section 11.4(c) outlines procedures for determining the responsible party for each clinical trial subject to this part. The Agency believes that there must be one (and only one) responsible party for each clinical trial subject to this part for which clinical trial information is submitted. Having only one responsible party for each clinical trial facilitates procedural requirements during registration and results information submission and prevents situations in which both a sponsor and a principal investigator consider themselves the responsible party and submit information for the same clinical trial. Absent a responsible party, the objectives of registration and results information submission cannot be met. The definition of responsible party under section 402(j)(1)(A)(ix) of the PHS Act specifies, first, that the sponsor will be the responsible party and, second, that the principal investigator is the responsible party if delegated this role through a designation "by a sponsor, grantee, contractor, or awardee." With regard to clinical trials, the Agency looks first to determine who is the sponsor of the clinical trial, consistent with the definition in this part, and assumes that such individual or entity is the responsible party, unless the principal investigator has been designated the responsible party in accordance with the procedure in § 11.4(c)(2). For a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party would be considered the entity FDA, under section 522 of the FD&C Act, orders to conduct the pediatric postmarket surveillance of a device product. In the final rule, § 11.4(c) clarifies that "device" means "device product."

Section 11.4(c)(1) specifies who will be considered the sponsor. The Agency believes that there must be a sponsor as that term is used in section 402(j)(1)(A)(ix) of the PHS Act for each clinical trial and that (as stated above) there can be only one sponsor. Without a defined sponsor, there cannot be a responsible party for a clinical trial because the responsible party is defined as either the sponsor or the principal investigator who has been so designated by the sponsor. The definition of sponsor in § 11.10(a) includes both a "sponsor" and a "sponsor-investigator" as those terms are defined in 21 Code of Federal Regulations (CFR) 50.3. or any successor regulation. Both definitions in 21 CFR 50.3 refer to the sponsor as, in part, the person or entity who "initiates" the clinical investigation. For purposes of this rule, if a clinical trial is being conducted under an IND or investigational device exemption (IDE), the IND/IDE holder is considered to be the individual or entity who initiated the clinical trial and, therefore, the sponsor, regardless of how the clinical trial is being funded. For clinical trials not conducted under an IND or IDE, the sponsor is considered to be the person or entity who initiated the trial and would be identified as follows:

(1) Where the clinical trial is being conducted by an entity under a research assistance funding agreement such as a grant or sponsored research agreement, the funding recipient generally is considered to be the initiator of the clinical trial, and therefore, the sponsor. This is because, as a general rule, when a clinical trial is funded in this manner, the funding recipient "initiates" the clinical trial process by, for example, submitting a funding proposal and designing the clinical trial.

(2) Where the clinical trial is being conducted by an entity under a procurement funding agreement such as a contract, the party obtaining the goods or services for its direct benefit or use (the funder) generally is considered to be the initiator of the trial, and therefore, the sponsor. This is because, as a general rule, when a clinical trial is funded in this manner, it is the funder of the clinical trial that initiates the clinical trial process by, for example, contracting with another entity for that entity to conduct a clinical trial meeting the specifications of the funder.

(3) Where there is no funding agreement supporting the clinical trial, the person or entity who initiated the clinical trial by preparing and/or planning the clinical trial, and who has appropriate authority and control over the clinical trial to carry out the responsibilities under section 402(j) of the PHS Act (including this part) is the sponsor.

Furthermore, § 11.4(c)(2) establishes the procedures for designation of a principal investigator as the responsible party. Section 402(j)(1)(A)(ix) of the PHS Act defines the responsible party, as either "the sponsor of the clinical trial" (as defined in [21 CFR 50.3] (or any successor regulation)); or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee," so long as such person meets certain criteria. In order to give practical effect to this provision, we conclude that, for any given applicable clinical trial or other clinical trial subject to this part, only one entity—the sponsor—can designate the principal investigator as the responsible party. We believe this interpretation is consistent with section 402(j) of the PHS Act because in many situations the sponsor of the clinical trial will also be a grantee, contractor, or awardee. In addition, interpreting this provision in a different manner could result in situations in which both a sponsor (*e.g.*, an IND/IDE holder) and a principal investigator (designated by a separate grantee, contractor, or awardee) consider themselves the responsible party and submit information for the same clinical trial. This would not only increase the overall burden associated with registration, but more importantly would undermine the integrity of the data bank and potentially cause confusion to users of the system.

Section 402(j)(1)(A)(ix) of the PHS Act permits a principal investigator to serve as a responsible party only if he or she "is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under [section 402(j) of the PHS Act] for the submission of clinical trial information." Accordingly, if the principal investigator does not meet the specified conditions for serving as the responsible party, the sponsor cannot designate the principal investigator as the responsible party, and the sponsor must remain the responsible party. In § 11.10(a) we define, for purposes of this part, the term principal investigator to mean "the individual who is responsible for the overall scientific and technical direction of the study." We note that under section 402(j)(1)(A)(ix) of the PHS Act, in order to be designated the responsible party, the principal investigator must be responsible for "conducting the trial" and must have "access to and control over the data from the clinical trial." We interpret "the trial" to refer to the "clinical investigation" as defined in 21 CFR 312.3 and this part, and to mean "the entire clinical investigation." Similarly, we interpret "the data" to mean "all of the data," including data collected at all sites of a multi-site trial.

To clarify our understanding of section 402(j)(3)(C)(iv) of the PHS Act as it relates to whether a principal investigator would be eligible to serve as the responsible party, this section requires the responsible party to indicate, as an element of clinical trial results information, whether there exist "certain agreements," which are described, with certain exceptions, as "an agreement . . . that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial." We do not view the presence of such an agreement as necessarily disqualifying a principal investigator from serving as the responsible party. Rather, we view only those agreements that prevent the principal investigator from performing the functions described in section 402(j)(1)(A)(ix)(II) of the PHS Act and § 11.4(c)(2)(i) of this part or from submitting clinical trial information or any updates to such information required by section 402(j) of the PHS Act and this part as preventing the principal investigator from serving as the responsible party.

To provide for the orderly implementation of section 402(j)(1)(A)(ix)(II) of the PHS Act, pursuant to which the sponsor may designate a principal investigator as the responsible party, and ensure that the principal investigator has notice of the designation, we have detailed the process in § 11.4(c)(2)(ii) for designating a principal investigator. It indicates that the sponsor shall provide notice of the designation to the principal investigator and obtain acknowledgement of the principal investigator's understanding of their responsibilities under this part. We intend to continue to provide mechanisms in the PRS for the sponsor and the principal investigator to indicate the designation and the acknowledgement, respectively. The designation by the sponsor is currently reflected in *ClinicalTrials.gov* by having the principal investigator submit clinical trial information via the sponsor's organizational account (the sponsor must provide an account for the principal investigator within the sponsor's PRS organizational account). The acknowledgement is reflected by having the principal investigator list their name as the responsible party and indicate that they were designated as the responsible party by the sponsor.

This approach has been available in *ClinicalTrials.gov* since 2011.

If and when a designated principal investigator no longer meets or is no longer able to meet all of the requirements of a responsible party, § 11.4(c)(3) outlines the mechanisms by which, if the withdrawal of such designation occurs, the sponsor would become the responsible party. This might occur if, for example, a principal investigator dies, retires, changes jobs, or turns control of the clinical trial data over to the sponsor. Final § 11.4 modifies the NPRM approach by clarifying in § 11.4(c)(3) that the sponsor, and not the clinical investigator, must withdraw the designation of a principal investigator as the responsible party. Because of this clarification, proposed § 11.4(c)(3)(ii) is no longer necessary, so § 11.4(c)(3)(i) is designated as § 11.4(c)(3).

We note that even if a sponsor designates a principal investigator as the responsible party for an applicable clinical trial registered under § 11.22, there may be times when the sponsor would need to provide the principal investigator with certain information in order for the principal investigator to meet the obligations of the responsible party. For example, in order for a principal investigator who has been designated as the responsible party to satisfy the conditions for submitting a certification for delayed submission of results information under § 11.44(b) or (c), the sponsor would likely have to provide the investigator with information about the conditions involving FDA action on a product application or submission, such as approval, that would require the responsible party to submit clinical trial results information as set forth in § 11.44(b) or (c).

Although we expect that a principal investigator who has been designated as the responsible party to request such information from the sponsor, we also expect a sponsor who has designated a principal investigator as the responsible party to provide appropriate information in a timely fashion. A principal investigator who is not provided the information necessary to enable him or her to meet all of the requirements for submitting and updating clinical trial information does not meet the criteria set forth in § 11.4(c)(2)(i) to serve as the responsible party. If the sponsor does not provide the principal investigator with the requisite information to meet the criteria under § 11.4(c)(2)(i), the principal investigator cannot be designated, or continue to act, as a responsible party and the responsible party would be, or would revert to, the sponsor.

3. 11.6—What are the requirements for the submission of truthful information?

Overview of Proposal

Section 402(j)(5)(D) of the PHS Act specifies that "clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular." In addition, the NPRM described other federal laws that address the submission of false or misleading information to the Federal Government (79 FR 69597). Specifically, it is a prohibited act under section 301(jj)(3) of the FD&C Act to submit clinical trial information under section 402(j) of the PHS Act that is false or misleading in any particular. In addition, other federal laws govern the veracity of information submitted to the Federal Government, such as 18 U.S.C. 1001 (making it a crime to make certain false statements to the executive, legislative, or judicial branch of the U.S. Government).

Proposed § 11.6 set out the requirements for the submission of truthful information. Proposed § 11.6(a) stated that submitted clinical trial information must not be false or misleading and that submission of such information may subject the responsible party to civil or criminal liability. Proposed § 11.6(b) required the responsible party to certify that submitted information is truthful and not misleading and that the responsible party is aware of the potential consequences of submitting such information. The certification was intended to ensure that responsible parties are aware of these statutory requirements and to provide an opportunity for them to attest to the veracity of the information at the time of submission.

Comments and Response

Commenters addressed proposed § 11.6. While no commenters disagreed with the proposal to include an explicit requirement that submitted clinical trial information must not be false or misleading and that a warning that submission of such information would subject the responsible party to civil, criminal, and/or administrative liability, commenters did address the proposal to require responsible parties to certify that submitted information is truthful and not misleading and that the responsible party is aware of the potential consequences of submitting such information. Several commenters noted that Title VIII of FDAAA did not stipulate that the Agency should require such a certification in the context of submissions to *ClinicalTrials.gov.* They also suggested that the requirement effectively duplicated three other statutory requirements beginning with two provisions in Title VIII of FDAAA that require the information submitted to *ClinicalTrials.gov* to not be false or misleading (section 282(j)(5)(D) of the PHS Act), which is reflected in proposed § 11.6(a) and the requirement that sponsors submit a certification to accompany the product applications or submission to FDA stating that the sponsor is in compliance with Title VIII of FDAAA (section 282(j)(5)(B) of the PHS Act), and reflected in the prohibited acts provisions (21 U.S.C. 331(jj)(3). They also pointed to the statutory prohibition on making false statements to the Federal Government at 18 U.S.C. 1001, which carries criminal penalties.

One commenter questioned the appropriateness of requiring responsible parties to certify that information submitted is not misleading due to a concern about how members of the public might react to the information. The concern was related to the fact that the structured nature of the database limited the responsible party's ability to provide clarifying contextual information, which if allowed to be provided, in the view of the commenter, would minimize the possibility of misleading a reader about some aspect of the clinical trial. The commenter also suggested that the proposed certification requirement would require a responsible party to evaluate whether providing the submitted information could "mislead" a member of the public and that, if the responsible party concluded that such a result were even remotely possible, they would be in an untenable position of having to reconcile conflicting legal obligations (*i.e.,* the responsible party could not satisfy its legal obligation to submit the clinical trial information under the PHS Act without certifying otherwise).

Commenters suggested alternatives to the certification requirement. One suggested that the requirement be reworked to focus on assuring that the submitted information is "truthful and complete" rather than the subjective "not misleading." Another suggested that it would be more appropriate to require the responsible party to certify that "the information contained in this submission is accurate to the best of the sponsor's knowledge." Notwithstanding the general support expressed for § 11.6, and although we do not agree that providing structured data entry in standard data formats could lead to misinterpretations of the data, we conclude that the commenters who addressed proposed § 11.6(b) specifically raised some valid concerns. The commenters suggested that responsible parties are well aware that they are legally bound to submit truthful information to the Federal Government and that a specific attestation to the veracity of the information at the time of information submission to *ClinicalTrials.gov* is unnecessary. As such, and given the other provisions in section 402(j) of the PHS Act that protect against the submission of false or misleading information, we have decided to drop the requirement that the responsible party certify that submitted information is truthful and not misleading and that the responsible party is aware of the potential consequences of submitting such information. With regard to the hypothetical concern that providing structured data entry in standard data formats could lead to misinterpretations of the data, it is important to note that we are not aware that such misunderstandings have occurred nor did any comments identify a specific example. Section 11.6(a) will be retained as a stand-alone provision of the final rule.

Final Rule

The final rule eliminates proposed § 11.6(b) and retains the requirement that submitted clinical trial information must not be false or misleading. The final rule also clarifies in § 11.6 that a responsible party who submits false and/or misleading information may be subject to civil monetary penalties and/or to other civil or criminal remedies available under U.S. law. Eliminating proposed § 11.6(b) does not change the responsible party's obligation to be truthful and not misleading in submissions to *ClinicalTrials.gov*.

4. 11.8—In what format must clinical trial information be submitted?

Overview of Proposal

Section 402(j)(3)(D)(v)(I) of the PHS Act requires the establishment of a "standard format" for the submission of clinical trial information. Section 402(j)(2)(B) of the PHS Act also requires that clinical trial information be submitted in such a way that is searchable by the public. Proposed § 11.8 set forth the required format for submitting clinical trial information to *ClinicalTrials.gov*. The proposal specified that information must be submitted electronically to *ClinicalTrials.gov* in the format specified at *http://prsinfo.clinicaltrials.gov* and explained that no other format would be accepted. Although the proposal used the phrase "form and manner" instead of "format," we are using "format" in the final rule to be consistent with the language of the statute in section 402(j)(3)(D)(v)(I). As discussed in sections II.B and III.C.10 of the NPRM, NLM is adopting a tabular, structured data entry system to promote objective reporting, optimize data display, permit effective searching of *ClinicalTrials.gov*, and facilitate cross-trial comparisons.

Proposed §§ 11.10, 11.28, and 11.48 specified the individual data elements of clinical trial information that must be submitted to *ClinicalTrials.gov* at the time of registration and results information submission (and updated in accordance with proposed § 11.64), including the subelements that are considered to be part of a data element (*e.g.*, proposed § 11.10(b)(5) specifies that the Study Design data element includes the subelements Interventional Study Model, Number of Arms, Arm Information, Allocation, Masking, and Single Arm Controlled).

In sections IV.B.4 and IV.C.4 of the NPRM, we described the specific format in which data elements and subelements would be required to be submitted to *ClinicalTrials.gov*. For some data elements and subelements, responsible parties would be required to submit information in free-text form. For other data elements and subelements, responsible parties would be required to select the best response from menus of options presented in *ClinicalTrials.gov*. The Agency also developed a mechanism for uploading registration and results data in an automated electronic fashion using eXtensible Markup Language (XML) files.

We explained in the NPRM preamble that the Agency might make minor changes from time to time to the specific format in which responsible parties would be required to submit individual data elements and subelements to *ClinicalTrials.gov* (79 FR 69598). We indicated that we would provide prior notice and seek public comment on any proposed changes to the format of submitting clinical trial information and that any changes would ultimately be reflected in the PRS.

We invited comment on the specific format described in the proposed rule for submitting data elements and subelements of proposed clinical trial information, including comments on the benefits and burden associated with providing proposed data elements and subelements, whether proposed menu options are sufficient to accommodate the range of potential entries (*e.g.*, for different trial designs), and whether an "other" option is needed in additional data elements (79 FR 69598). We also invited comment on the proposed approach described in this section for modifying the format of submitting clinical trial information over time.

Comments and Response

Commenters addressed the proposed format of submission. Some comments explicitly supported the proposed rule requirements for information to be submitted in a structured format. Other comments addressed data formatting issues in the PRS. Some of these commenters recommended that the PRS allow submissions in Microsoft Excel® files, such as for adverse events, particularly because academic medical centers are generally not familiar with XML. We note that the PRS system has allowed for the submission of adverse event information in spreadsheet format, including Excel, since 2013 and will continue to allow this format.

Other commenters requested that the PRS accept submissions in the same electronic formats as required by the Agency and other federal funders for submissions to their own databases (*e.g.*, Clinical Trial Reporting Program (CTRP) for the National Cancer Institute (NCI)). This approach of broadly accepting the same electronic format as other systems is not feasible. Any single standard data format adopted by *ClinicalTrials.gov* must provide sufficient generality and flexibility to accommodate accurate reporting of the mandated clinical trial information for a wide range of clinical trial designs, research areas/domains, and funder/sponsor classes covered by the law. While the Agency appreciates that accepting a variety of submission formats from other federal databases may be less burdensome for responsible parties, the PHS Act requires the final rule to establish a standard format for the submission of clinical trial information. This standard format will, in turn, facilitate search and comparison of entries in the registry data bank, as is also required under the statute. Furthermore, it is possible for other systems to map their content to the standard data format at *ClinicalTrials.gov*. For example, because the data elements used to describe a clinical trial in the NCI's CTRP are designed to be compatible with the standard format required for submitting clinical trial registration information to *ClinicalTrials.gov*, responsible parties who have previously submitted trial information to CTRP can submit that same information directly into the PRS at *ClinicalTrials.gov*. NCI intends to continue to ensure that the information collected in CTRP is compatible with the requirements of the final rule, while continuing to collect and maintain other information that meets distinct CTRP purposes. NIH is also taking steps to bring more standardization to the information obtained from clinical trial applicants and awardees in order to enhance its stewardship of clinical trials. These efforts will also take into consideration the data elements in *ClinicalTrials.gov.*

ClinicalTrials.gov supports this information exchange by making available to all organizations the specific data elements and their definitions, an XML schema, an application program interface (API), and information about validation messages. We, therefore, retain the PRS submission format in the final rule in order to meet the requirements of the law, but will continue to allow responsible parties who have previously submitted clinical trial data elements to a number of other databases that are compatible with the PRS standard format to transfer clinical trial information automatically from those databases into *ClinicalTrials.gov.*

Some commenters recommended the use of the Clinical Data Interchange Standards Consortium (CDISC) data format to ensure harmonization for registration and results information reporting. To our knowledge, there is no existing standard data format that supports the entirety of the requirements in the final rule. However, if such a standard data format is developed and adopted by a significant number of responsible parties, the Agency will work to provide appropriate interfaces for providing information in that format. In general, the PRS will accept XMLs that meet the requirements of the PRS and that include information that satisfies the elements and subelements required in this regulation.

A number of commenters also stressed the importance of harmonization with international and other standard data formats for uniformity in registration and results information submissions. Some commenters requested that data formats be made consistent and be harmonized with databases such as the EU EudraCT database administered by the EMA [Ref. 70], or the WHO International Clinical Trial Registry Platform Trial Registration Data Set (Version 1.2.1) [Ref. 73]. One commenter requested specifically that any new data technologies and database functionalities should be consistent with the EU and other registration databases.

We note that the NPRM preamble identified data elements that are consistent with the WHO Trial Registration Data Set (*i.e.,* brief title, official title, study design, primary disease or condition being studied in the trial, focus of the study, intervention name, primary and secondary outcome measures, eligibility criteria, overall recruitment status, and secondary identifications (IDs)) (79 FR 69611 et al). These data elements are maintained in the final rule. In addition, the Agency provided technical assistance to the EMA during development of the EudraCT results database so that EudraCT's data requirements are substantially aligned with the requirements for *ClinicalTrials.gov* [Ref. 71]. Also, in April 2015, WHO issued a Statement on Public Disclosure on Clinical Trial Results [Ref. 74]. Although section 402(j)(3)(D)(vi) of the PHS Act requires the Agency to consider the status of consensus data elements set of the WHO for reporting clinical trial results information, the WHO's April 2015 statement did not include any consensus data elements. The Agency notes that opportunities to incorporate newer data formats in the future will be available through the procedures described for format changes in the section below.

One commenter requested that the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT®) be used for terminology, or in the alternative ICD–10, to ensure the standard's ability to ''map'' to electronic health records. SNOMED CT® is a comprehensive clinical terminology owned, maintained, and distributed by the International Health Terminology Standards Development Organization [Ref. 75], which includes NLM as the U.S. member. SNOMED CT® is used in systems of the Federal Government for the electronic exchange of clinical health information and is a required standard data format in interoperability specifications of the U.S. Healthcare Information Technology Standards Panel [Ref. 76]. Since SNOMED CT® provides clinical terminology, it applies most directly to the data element of ''primary disease or condition being studied in the trial, or focus of the study'' (§ 11.10(b)(9)). We note that the rule allows the use of SNOMED CT® for this data element or any other vocabulary that has been mapped to Medical Subject Headings (MeSH®) [Ref. 77] with the Unified Medical Language System (UMLS) Metathesaurus. The use of ONC-certified or endorsed terminologies is encouraged where possible, including, but not limited, to SNOMED CT and Logical Observation Identifiers Names and Codes, known by its acronym LOINC®.

Finally, some comments requested that an ''Other'' category option be provided for all data elements. We have instead included an ''Other'' category as menu options only for those data elements where we believe it is necessary and appropriate. In some instances, such as for Study Phase and Study Type, the menu list is comprehensive and no ''Other'' category is needed. An advantage of providing a comprehensive list of substantive options, when possible, is to mitigate confusion and potential errors during data entry. Another key advantage of using only controlled terms as menu items is that it increases structure of the database, thereby facilitating accurate search and complete information retrieval. Allowing the selection of an ''Other'' option with additional free-text elaboration can limit the specificity and searchability of the database. Thus, we have limited the number of data elements that provide an ''Other'' category as an option. As the nature of clinical research methodologies and practices evolve and we gain more experience with certain data elements, we anticipate that menu options will likely change. As described in more detail in the final rule discussion for § 11.8, we will use a notice-and-comment process before adding any new menu options for a data element.

Final Rule

The final rule maintains § 11.8, with some modification for further clarity, in requiring ''Information submitted under this part must be submitted electronically to *ClinicalTrials.gov,* in the format specified at *https://prsinfo.clinicaltrials.gov.*'' The final rule also modifies in the section title the phrase ''form and manner'' to ''format'' to be consistent with the language used in section 402(j)(3)(D)(v)(I) of the PHS Act.

This final rule also specifies the data elements and subelements defined in § 11.10 and required by § 11.28 and § 11.48. In addition, by describing the registration and results information to be submitted to *ClinicalTrials.gov,* this final rule preamble specifies the format in which information will be submitted (such as free text or menu selections). The format specified in this final rule preamble will be described at *https://prsinfo.clinicaltrials.gov* (or successor site). The choice of providing menu options versus free-text fields and the set of menu options offered for specific data elements and subelements are based on our experience in operating *ClinicalTrials.gov* and on comments received from users of *ClinicalTrials.gov,* including those who commented on the FDA draft and final guidance documents that were issued in 2002 and 2004 [Ref. 78, 79] (79 FR 69570) and the preliminary version of the results database and adverse event module that were available for testing beginning in the spring of 2008 (73 FR 29525). Some menus offer a fixed set of options without an ''Other'' option; others offer a prespecified set of options plus an ''Other'' option. In most cases, responsible parties selecting the ''Other'' option would be required to provide a free-text response to elaborate on the ''Other'' selections. Some data elements without an ''Other'' option also include an optional free-text field in which responsible parties could voluntarily provide additional information about the option selected.

The use of menu options is intended to promote the entry of data in a structured format that allows users to search *ClinicalTrials.gov* and retrieve comparable information, consistent with the requirements of sections 402(j)(2)(B) and (3)(D)(v)(I) of the PHS Act. Menu options have been used in *ClinicalTrials.gov* since its launch and are routinely used to improve the quality and to help ensure the completeness of data submitted to information systems. Their use can reduce typographical errors in data entry and minimize the data entry burden on responsible parties by providing a set of predefined options for common entries. By standardizing the set of available responses, they also promote the use of consistent terminology across entries and can improve the ability of users to search the data bank and compare entries easily across clinical trials.

We further note that to reduce the burden on responsible parties related to the submission of information to the data bank, *ClinicalTrials.gov* accommodates both interactive, online entry of information for a specific clinical trial and automated uploading of information that is prepared in XML format. Responsible parties submitting information on multiple clinical trials may upload information that is prepared as a batch submission. *ClinicalTrials.gov* also supports uploading of adverse event information using a spreadsheet program, such as Microsoft Excel®, so long as it conforms to the specified data format of the PRS. Additional information about submitting information to *ClinicalTrials.gov* is available at *https://prsinfo.clinicaltrials.gov.*

As described in the NPRM, the Agency might periodically make minor changes to the specific format in which responsible parties submit individual data elements and subelements to *ClinicalTrials.gov* (79 FR 69598). Such changes would not require a responsible party to submit different or more clinical trial information than is specified in the final rule, but would alter the way in which the information is entered, with the general aim of making sure the menu options contain the most relevant, useful, and convenient options for responsible parties and users of the system. For example, if the research community develops a new type of clinical trial design, we might expand the list of menu options under the Interventional Study Model subelement of the Study Design data element to include it. If we find that many of the free-text entries for the Why Study Stopped data element fall into a small number of categories, we might offer them as menu options (in addition to accepting free-text for ''Other'' reasons) to reduce the burden of data entry and improve the consistency and comparability of responses across registered clinical trials. We will provide prior notice and seek public comment on any proposed changes of substantive nature to the format of submitting clinical trial information. There may be times when changes of a technical nature may be required (*e.g.,* updates to the XML, redesign of the user interface, modifications to PRS on-screen instructions), for which no public comments will be sought.

5. 11.10—What definitions apply to this part?

Section 11.10 of the NPRM defined certain terms and data elements used in the proposed part. The terms defined in proposed § 11.10(a) included terms explicitly defined in section 402(j) of the PHS Act (*e.g.,* ''applicable clinical trial,'' ''responsible party''); terms used but not defined in section 402(j) of the PHS Act (*e.g.,* ''clinical trial''); and terms not specifically found in section 402(j) of the PHS Act but which are important for implementing the statutory provisions. With respect to terms not defined in the statute, we proposed definitions to fit within the proposed framework for the expanded data bank and for the purposes of satisfying the statutory goals, clarifying the application and operation of this proposed rule, in particular as related to information to be submitted to *ClinicalTrials.gov,* and/or for convenience. We also referenced some terms defined under the PHS Act and the FD&C Act and implementing regulations, as necessary.

For each term defined in proposed § 11.10(a), we describe below the proposed definition, any specific public comment(s) we received and our response(s), and the term and definition that is adopted in § 11.10(a) of the final rule. The list below is alphabetized according to the name assigned to the term in the final rule. For example, the term ''FDA-regulated device'' proposed in the NPRM is ''U.S. FDA-regulated device'' in the final rule, so it appears toward the end of the list.

Adverse Event

In the NPRM, we defined ''adverse event'' in § 11.10(a) as ''any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to subject's participation in the research.''

As we explained in the NPRM, ''adverse event'' is a term used but not defined in section 402(j)(3)(I) of the PHS Act to describe a certain category of clinical trial results information (79 FR 69598). Section 402(j)(3)(I)(iii) of the PHS Act requires the reporting of both anticipated and unanticipated adverse events. Current FDA regulations define the term ''adverse event'' with respect to drugs, but not to devices. (FDA regulations for devices include a different but related term, ''suspected adverse device effect,'' that is discussed in the definition of the term ''serious adverse event.'') FDA regulations for IND safety reporting requirements that were issued on September 29, 2010 (75 FR 59935), and took effect on March 28, 2011 define an adverse event as ''any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related'' (21 CFR 312.32(a)). In addition to defining the term ''adverse event,'' those FDA regulations have the additional purpose of identifying circumstances in which certain adverse events (such as those that are serious and unexpected and that also meet the definition of a ''suspected adverse reaction,'' meaning that the adverse event must have a reasonable possibility of being caused by the drug) must be reported in an expedited fashion while the trial is ongoing.

The HHS Office for Human Research Protections (OHRP) has a definition of adverse event that covers drug, device, and other interventions and includes both anticipated and unanticipated event(s) regardless of whether they are attributed to the intervention(s) studied in the clinical trial. As discussed in OHRP's "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events" (January 2007), an adverse event means "[a]ny untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research" [Ref. 80]. The OHRP definition was adapted from the definition used by the International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use (ICH) Guideline E6, Good Clinical Practice: Consolidated Guidance [Ref. 81] which was published by FDA as a guidance document in the FR in 1997 (62 FR 25692). The definition, therefore, is consistent with international norms. Although the ICH Guidelines are intended to apply to pharmaceutical products, the OHRP definition is intended to apply broadly to research in humans that involves any type of intervention.

We received comments on the adverse event definition. The commenters asserted that the definition was inconsistent with FDA's adverse event definition. One commenter noted that the definition of "adverse event" was vague and requested that the rule define the term to be consistent with IRB reporting requirements at continuing review. We disagree. The IRB requirements cited by the commenter are described in the OHRP guidance from which we derived the adverse event definition; this helps ensure consistency in the submission of adverse event information for applicable device clinical trials and applicable drug clinical trials. As explained above, this definition is consistent with, but not identical to, FDA's definition of "adverse event" for IND safety reporting in 21 CFR 312.32(a). The definition in § 11.10(a) includes not only those adverse events defined in 21 CFR 312.32 (which apply to clinical trials of drug products), but also adverse events more broadly from research participation subject to this part (*i.e.,* including clinical trials of device products) and ensures consistency with the international standard. For example, a "suspected adverse event," defined by FDA as a subcategory of "adverse event" that requires a reasonable possibility of being caused by the drug, is also included under the definition of "adverse event" in § 11.10(a).

After considering these comments, we maintain the definition of "adverse event" in § 11.10(a) of the final rule to mean "any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to subject's participation in the research."

Additionally, this final rule includes a requirement to submit to *ClinicalTrials.gov* summary information about anticipated and unanticipated adverse events observed during a clinical trial (as well as a requirement to submit information about serious adverse events), regardless of attribution (*i.e.,* whether or not the investigator believes they are related to the intervention(s)). These requirements are consistent with the definition of "adverse event" in the final rule, which is not limited to adverse events that are anticipated, are likely to have been caused by the drug product (including biological product) or device product (or other type of intervention used in the clinical trial), or have a reasonable possibility of being related to the intervention under study. The definition of "adverse event," which includes all adverse events regardless of possible attribution and regardless of whether they were anticipated, advances the statutory goal of providing more information that may be related to medical products' potential risks.

Applicable Clinical Trial

In the NPRM, we defined "applicable clinical trial" in § 11.10(a) to mean "an applicable device clinical trial or an applicable drug clinical trial." As we explained, this definition, which is identical to the statutory definition in section 402(j)(1)(A)(i) of the PHS Act, designates the scope of clinical trials that may be subject to the requirements to submit clinical trial registration and results information as specified in this part (79 FR 69599). However, not all trials meeting the definition of an "applicable clinical trial" are subject to the clinical trial registration and results information submission requirements. For example, an applicable clinical trial that reached its primary completion date on or before September 27, 2007 (*i.e.,* the date of enactment of FDAAA) is not subject to section 402(j) of the PHS Act, nor is an applicable clinical trial that was ongoing as of September 27, 2007, and reached its primary completion date prior to December 26, 2007. In addition, in proposed § 11.22(b), we described an approach for determining whether a clinical study or trial meets the definition of an "applicable clinical trial."

We received comments on this definition. One commenter supported the proposed definition. Other commenters requested that the definition include all clinical trials, and one of these commenters further requested that the definition be amended in the final rule to include any human experiment introducing any form of a drug, device, biologic, radiation, or any other form of treatment into the human body. The definition of "applicable clinical trial" is set forth in section 402(j) of the PHS Act.

Based on further review and analysis, we have reconsidered whether any expanded access use falls within the definition of "applicable clinical trial." For the following reasons, we have determined that no expanded access use would be considered an "applicable clinical trial" under section 402(j) of the PHS Act.

FDAMA (Pub. L. 105–115) contained two related provisions addressing expanded access use. FDAMA added section 561 to the FD&C Act, which specifically authorized the Secretary to permit investigational drugs and investigational devices to be made available for the diagnosis, monitoring, or treatment of serious or life-threatening diseases or conditions under certain circumstances. These so-called "expanded access" provisions were implemented by FDA through its IND and IDE regulations (see 21 CFR 312.300–320 and 21 CFR 812.36).

FDAMA also amended section 402 of the PHS Act to require the Secretary to establish a data bank of information on experimental drugs for serious or life-threatening diseases and conditions. This FDAMA-created data bank included two specified aspects: "(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 505(i) of the [FD&C Act] . . ." and "(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—(i) under a treatment investigational new drug application that has been submitted . . . under section 561(c) of the [FD&C Act] . . ." (currently section 402(i)(3) of the PHS Act). In addition, the FDAMA data bank could include information on "the results of clinical trials . . . with the consent of the sponsor . . .'' (currently section 402(i)(3) of the PHS Act).

These FDAMA provisions were implemented by NIH through the creation of *ClinicalTrials.gov*. The FDAMA provisions were subsequently amended to require information on clinical trials to also include a description of whether, and through what procedure, the manufacturer or sponsor would make the drug available for expanded access use, particularly in children (section 15(c)(2) of Public Law 107–109; 115 Stat. 1420 (2002)). Thus, there is a distinction reflected in section 402(i) of the PHS Act between a clinical trial and expanded access use.

The FDAAA provision adding current section 402(j) of the PHS Act was intended to expand the *ClinicalTrials.gov* data bank. The structure and language of section 402(j) reflect congressional intent to maintain in the data bank the same distinction between clinical trials and expanded access use. This congressional intent is evident in section 402(j)(2)(A)(ii)(II)(gg) of the PHS Act, which states that ''in the case of an applicable drug clinical trial, if the drug is not approved . . . specify whether or not there is expanded access to the drug under section 561 of the [FD&C Act] . . .'' This provision implies that expanded access use would not itself be considered an ''applicable clinical trial.''

For these reasons, we have concluded that expanded access use under section 561 of the FD&C Act does not fall within the definition of ''applicable clinical trial'' under section 402(j) of the PHS Act. However, information on the availability of investigational drug products (including biological drug products) for expanded access will continue to be required to be submitted to the *Clinical Trials.gov* database under authority of the section 402(j) registration requirements.

In the final rule, the definition of ''applicable clinical trial'' in § 11.10(a) is revised by the addition, at the end of the definition, of the following statement: ''Expanded access use under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is not an applicable clinical trial.'' Other than this change, we maintain the proposed definition of ''applicable clinical trial'' as the first sentence of the definition in the final rule: ''Applicable clinical trial means an applicable device clinical trial or an applicable drug clinical trial.'' This first sentence of the definition is identical to the statutory definition.

We also received comments specifically on the ''applicable device clinical trial'' or ''applicable drug clinical trial'' components of the proposed applicable clinical trial definition. These are addressed within the definition for each.

Applicable Device Clinical Trial

In the NPRM, we defined ''applicable device clinical trial'' in § 11.10(a) to mean (1) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the FD&C Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and (2) a pediatric postmarket surveillance as required under section 522 of the FD&C Act.

As we explained in the NPRM, ''applicable device clinical trial'' is the term used in section 402(j)(1)(A) of the PHS Act to designate the clinical trial of a device and FDA-ordered pediatric postmarket surveillance of a device for which clinical trial information must be submitted to *ClinicalTrials.gov* under section 402(j) of the PHS Act (79 FR 69599). The proposed rule adopted, in § 11.10, the definition of applicable device clinical trial, as provided in section 402(j)(1)(A)(ii) of the PHS Act: ''(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the [FD&C] Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and (II) a pediatric postmarket surveillance as required under section 522 of the [FD&C] Act.'' In addition, the proposed rule in § 11.10 adopted the definition of ''device'' in section 402(j)(1)(A)(vi) of the PHS Act as ''a device as defined in section 201(h) of the [FD&C] Act.'' We provided additional elaboration of the interpretation of applicable device clinical trial in the NPRM.

We received several comments on this definition. One commenter supported the proposed rule's applicable clinical trial definition with respect to devices, particularly that only a ''prospective'' clinical study should be considered an ''interventional study,'' and thus an applicable clinical trial. Many commenters requested that the applicable device clinical trial definition be expanded to include any trials in which a device is introduced into the human body, but they agreed that the definition should not include observational studies. One commenter requested that the definition include small device feasibility studies, which are explicitly excluded by the statutory definition. Two other commenters requested that the definition include all studies conducted under an IDE.

We have not modified the definition of ''applicable device clinical trial'' in the final rule based on these comments. The statutory definition explicitly states which trials fall within the definition of an applicable clinical trial; it does not include all device clinical trials. Section 402(j)(1)(A)(ii) of the PHS Act requires that the device must be subject to section 510(k), 515, or 520(m) of the FD&C Act. Section 402(j)(1)(A)(ii) of the PHS Act also explicitly excludes certain device feasibility studies from the ''applicable device clinical trial'' definition. A device is considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act if any of the following is required before it may be legally marketed in the United States: (1) A finding of substantial equivalence under section 510(k) of the FD&C Act permitting the device to be marketed, (2) an order under section 515 of the FD&C Act approving a pre-market approval application for the device, or (3) a humanitarian device exemption (HDE) under section 520(m) of the FD&C Act. Such devices that are considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act include significant risk devices for which approval of IDE is required under section 520(g) of the FD&C Act, non-significant risk devices that are considered to have an approved IDE in accordance with 21 CFR 812.2(b), or devices that are exempt from the submission requirements of 21 CFR 812 (79 FR 69600).

Some commenters also requested clarification of definitional elements. One commenter requested that the rule clarify the term ''health-outcomes'' for making an applicable clinical trial determination. We have not provided a definition of ''health outcomes'' in the final rule for the applicable device clinical trial definition. However, in the NPRM, we explained that a ''prospective clinical study of health outcomes'' is a clinical study in which the primary objective is to evaluate a defined clinical outcome related to human health (79 FR 69599). For example, a clinical study of a diagnostic device (such as an in vitro diagnostic (IVD)) in which the primary purpose is to evaluate the ability of the device to make a diagnosis of a disease or condition is related directly to human health and, therefore, would be considered a clinical study ''of health outcomes'' for purposes of this rule. We will consider additional guidance on this term if our experience reflects it is needed.

Another commenter suggested that the term "feasibility," as used in the parenthetical exclusion in the definition of "applicable device clinical trial," was described in the NPRM in a way that is more limited than FDA guidance and requested clarification in the final rule. The "feasibility study" exclusion in the definition directly incorporates the language from section 402(j)(1)(A)(ii)(I) of the PHS Act: "a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes" is not an "applicable device clinical trial." We explained in the NPRM that clinical studies designed primarily to determine the feasibility of a device or to test a prototype device are considered by the Agency to be clinical studies conducted to confirm the design and operating specifications of a device before beginning a full clinical trial (79 FR 69601). Feasibility studies are sometimes referred to as phase 1 studies, pilot studies, prototype studies, or introductory trials (although we note that the use of these terms does not necessarily mean that the study is a feasibility study under the definition). Our explanation of this exemption is consistent with FDA's regulation of devices. FDA published the guidance *Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies* (October 2013) to address the development and review of IDE applications for early feasibility studies of significant risk devices [Ref. 82]. For the purposes of the guidance, the guidance defines an "early feasibility study" as a limited clinical investigation of a device early in development, typically before the device design has been finalized, for a specific indication. The guidance further defines a "traditional feasibility study" as a clinical investigation that is commonly used to capture preliminary safety and effectiveness information on a near-final or final device design to adequately plan an appropriate pivotal study. Section 402(j)(1)(A)(ii)(I) of the PHS Act excludes "small clinical trial[s] to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes" from the definition of "applicable device clinical trial." The excluded clinical trials described in this statutory definition appear to be consistent with the early feasibility study definition in the guidance, but not with that of the traditional feasibility study, which evaluates preliminary safety and effectiveness information (*i.e.,* for "health outcomes"). Therefore, it is likely that only early feasibility studies would fall within this exclusion under the § 11.10 definition of an "applicable device clinical trial."

Two commenters requested that the rule define "small," which is used in the definition's "feasibility study" exemption. One of the commenters requested that the rule use a "threshold" number of subjects indicated for the Enrollment data element based on an empirical database review, such as not more than 20–30 subjects for a study. The other commenter requested clarification of the term "small" and suggested that a device trial with at least 10 subjects could not qualify as "small" for the "feasibility study" exemption. We are not including a threshold number in the definition, because some studies with an enrolled subject total exceeding a specified threshold might be more appropriately considered a "small feasibility study," while other studies with an enrolled subject total below the specified threshold, depending on the prevalence of the disease or condition, might not be considered "small" for the purposes of this exemption. We note that a trial with at least 10 subjects would generally not be considered "small."

To determine whether a device trial is an applicable device clinical device, one comment requested clarification as to whether a device that is solely packaged and/or labeled in the United States would be considered "manufactured in" the United States. The commenter opposed considering devices that are solely packaged and/or labeled in the United States as "manufacture[d] in the U.S." and requested clarification in the final rule. Pursuant to section 510 of the FD&C Act, FDA's jurisdiction extends to the "manufacture, preparation, propagation, compounding or processing" of devices, which term is defined to include "repackaging or otherwise changing the container, wrapper, or labeling or any . . . device package in furtherance of the distribution of the . . . device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." The NPRM used the term "manufacture" as a short-hand for all device activities within FDA's jurisdiction. Therefore, a device product that is packaged and/or labeled in the United States would be considered "manufactured" in the United States and subject to section 510(k), 515, or 520(m) of the FD&C Act.

After considering the comments, we maintain the definition of "applicable device clinical trial" in § 11.10(a), except that we have clarified the status of certain clinical trials of combination products, made clear that the term "device" refers to a particular manufacturer's device product, and included the applicable United States Code (U.S.C.) statutory citations. In § 11.10(a) of the final rule, we define "applicable device clinical trial" to mean "(1) [a] prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes); (2) [a] pediatric postmarket surveillance of a device product as required under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l); or (3) [a] clinical trial of a combination product with a device primary mode of action under 21 CFR part 3, provided that it meets all other criteria of the definition under this part."

The first part of the definition in section 402(j)(1)(A)(ii)(I) of the PHS Act defines a clinical study as an applicable device clinical trial if it meets the following four criteria: (1) It is a prospective clinical study of health outcomes; (2) it compares an intervention with a device against a control in human subjects; (3) the studied device is subject to section 510(k), 515, or 520(m) of the FD&C Act; and (4) it is other than a small clinical trial to determine the feasibility of a device or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes. Except as described below with regard to pediatric postmarket surveillances of a device product, if a clinical investigation fails to meet one or more of these criteria, it would not be considered an applicable device clinical trial. We have considered the meaning of these criteria carefully and our interpretation follows.

(1) "Prospective clinical study of health outcomes." First, we interpret the term "clinical study," with respect to a device product. We interpret "clinical study" with respect to a device product to mean an investigation in which a device product is used in one or more human subjects. For the purposes of

interpreting the term "clinical study," we consider the term "human subject" to have the same meaning as the term "subject," which is defined in FDA regulations as a "human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease" (see 21 CFR 812.3(p)). For the purposes of only the requirements under section 402(j) of the PHS Act and this rule, the term "human subject" does not include de-identified human specimens [Ref. 83]. Note that we use the term "participant" interchangeably with "human subject" in this document.

The term "study" is often used interchangeably with the term "investigation." As pertaining to device products, "investigation" is defined as "a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device." (See 21 CFR 812.3(h).) Although FDA regulations pertaining to device products do not specifically define the term "clinical investigation," that term is defined in FDA regulations pertaining to clinical investigations of drug products (including biological products) as "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects," where "experiment" is defined as "any use of a drug except for the use of a marketed drug in the course of medical practice" (see 21 CFR 312.3). In our view, these definitions can be applied to trials of a device product by defining a "clinical study of a device product" as "any experiment in which a device product is administered, dispensed to, or used involving, one or more human subjects," defining an "experiment" as "any use of a device product except for the use of a marketed device product in the course of medical practice," and using the definition of "subject" described above (from 21 CFR 812.3(p)). This interpretation helps improve consistency between definitions of the terms "applicable device clinical trial" and "applicable drug clinical trial." In addition, our proposed interpretation of a "clinical study" of a device product would include studies in which subjects are assigned to specific interventions according to a study protocol. Studies in which a device product is used on a patient as part of routine medical care and not because of a study or protocol would not be considered clinical studies for the purposes of this rule. An example of studies that would not be considered clinical investigations include situations in which, after a device product has been administered to patients in the course of routine medical practice by a healthcare provider, a researcher not associated with the administration of the device product reviews the patients' records in order to assess certain effects, interviews the patients to assess certain impacts, or collects longitudinal data to assess health outcomes.

Second, turning to our interpretation of the term "prospective," we consider a prospective clinical study to be any study that is not retrospective or, in other words, one in which subjects are followed forward in time from a well-defined point (*i.e.,* the baseline of the study) or are assessed at the time the study intervention is provided. A prospective clinical study may also have non-concurrent (*e.g.,* historical) control groups. An example of a retrospective study, and therefore not an applicable device clinical trial, is a study in which subjects are selected based on the presence or absence of a particular event or outcome of interest (*e.g.,* from hospital records or other data sources) and their past exposure to a device product is then studied.

Third, with respect to our interpretation of the phrase "of health outcomes," for the purposes of the definition of "applicable device clinical trial," we consider a "prospective clinical study of health outcomes" to be a clinical study in which one or more of the primary or secondary outcome measures are biomedical or health-related. For example, a clinical study of a diagnostic device (such as an IVD) in which the primary outcome measure is the number of subjects with the correct diagnosis, would be considered a clinical study of health outcomes for the purposes of this proposed rule.

(2) "Comparing an intervention with a device against a control in human subjects." We interpret the phrase an "intervention with a device" to be an intervention in which a device product is used on a human subject in the course of a study. As stated above, the meaning of the term "human subject" is consistent with the definition of "subject" in 21 CFR 812.3(p), except that for the purposes of only the requirements under this part, the term "human subject" does not include de-identified human specimens. We interpret the term "intervention" broadly, to include various techniques for using the device product such as, among others, device regimens and procedures and the use of prophylactic, diagnostic, or therapeutic agents.

A clinical study is considered, or intended, to "compare an intervention with a device against a control in human subjects" when it compares differences in the biomedical or health-related outcomes between human subjects who received an intervention that included a device product and human subjects who received other interventions or no intervention (*e.g.,* comparison with another device product, comparison with usual clinical care that did not involve a device product). The intervention under study may be one with a device product that has never been cleared or approved or one with a device product that has been cleared or approved, regardless of whether the clearance or approval is for the use being studied. Such controlled clinical studies include not only concurrent control groups, but also non-concurrent controls such as historical controls (*e.g.,* literature, patient records, human subjects as their own control) or outcomes using objective performance criteria such as performance criteria based on broad sets of data from historical databases (*e.g.,* literature or registries) that are generally recognized as acceptable values. As discussed further in the definition of "control or controlled," we clarify for the purposes of this part that all interventional studies, whether single or multi-arm, with a pre-specified outcome are considered to be controlled (*i.e.,* comparing an intervention against a control).

As discussed above, expanded access protocols under section 561 of the FD&C Act, under which investigational devices are made available under certain circumstances, do not fall within the definition of "applicable device clinical trial."

(3) "A device subject to section 510(k), 515, or 520(m)" of the FD&C Act. A device product is considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act if any of the following is required before it may be legally marketed in the United States: (1) A finding of substantial equivalence under section 510(k) permitting the device product to be marketed, (2) an order under section 515 of the FD&C Act approving a pre-market approval application for the device product, or (3) an HDE under section 520(m) of the FD&C Act. Device products that are considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act include significant risk devices for which approval of an IDE is required under section 520(g) of the FD&C Act, non-significant risk devices that are considered to have an approved IDE in accordance with 21 CFR 812.2(b), or

device products that are exempt from the submission requirements of 21 CFR part 812.

If a clinical study of a device product includes sites both within the United States (including any U.S. territory) and outside of the United States, and if any of those sites is using (for the purposes of the clinical study) a device product that is subject to section 510(k), 515, or 520(m) of the FD&C Act, we would consider the entire clinical study to be an applicable device clinical trial, provided that it meets all of the other criteria of the definition under this part. However, a clinical study of a device product that is being conducted entirely outside of the United States (*i.e.,* does not have any sites in the United States or in any U.S. territory) and is not conducted under an IDE may not be a clinical study of a device product subject to section 510(k), 515, or 520(m) of the FD&C Act and, therefore, is not an applicable device clinical trial, depending on where the device product being used in the clinical study is manufactured. If the device product is manufactured in the United States or any U.S. territory, and is exported for study in another country (whether it is exported under section 801(e) or section 802 of the FD&C Act), the device product is considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act. If the device product is manufactured outside of the United States or its territories, and the clinical study sites are all outside of the United States and/or its territories, the device product would not be considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act. A device product that is packaged and/or labeled in the United States would be considered "manufactured" in the United States subject to section 510(k), 515, or 520(m) of the FD&C Act.

(4) "Other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes." Clinical studies designed primarily to determine the feasibility of a device product or to test a prototype device are considered by the Agency to be clinical studies conducted to confirm the design and operating specifications of a device product before beginning a full clinical trial. Feasibility studies are not considered applicable device clinical trials under this part.

The second part of the definition in section 402(j)(1)(A)(ii)(II) of the PHS Act specifies that an applicable device clinical trial includes "pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act." Postmarket surveillances can take many forms, from literature reviews to controlled clinical trials. Based on the statutory language, any pediatric postmarket surveillance of a device product under section 522 of the FD&C Act, regardless of its design, is an applicable device clinical trial.

In addition, a combination product may include a device subject to section 510(k), 515, or 520(m) of the FD&C Act, as well as a drug (including a biological product) subject to section 505 of the FD&C Act or section 351 of the PHS Act (see 21 CFR 3.2(e)). Drugs (including biological products) and devices do not lose their discrete regulatory identities when they become constituent parts of a combination product. In general, the regulatory requirements specific to each constituent part of a combination product also apply to the combination product itself. However, because some requirements of section 402(j) of the PHS Act are different for applicable device clinical trials than for applicable drug clinical trials, there is a need for clarity as to which requirements apply to applicable clinical trials of combination products that include device and drug constituent parts. In order to provide this clarity, the final rule specifies that an applicable clinical trial of a combination product with a device primary mode of action under 21 CFR part 3 would be considered an applicable device clinical trial, provided that it meets all other criteria of the definition under § 11.10(a), and likewise, a clinical trial of a combination product with a drug primary mode of action under 21 CFR part 3 would be considered an applicable drug clinical trial, provided that it meets all other criteria of the definition under § 11.10(a).

Applicable Drug Clinical Trial

In the NPRM, we defined "applicable drug clinical trial" in § 11.10(a) to mean "a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act, where 'clinical investigation' has the meaning given in 21 CFR 312.3 (or any successor regulation) and 'phase 1' has the meaning given in 21 CFR 312.21 (or any successor regulation)."

As we explained in the NPRM, "applicable drug clinical trial" is the term used in section 402(j)(1)(A) of the PHS Act to designate a clinical trial involving a drug (including a biological product) for which clinical trial information must be submitted to *ClinicalTrials.gov* under section 402(j) of the PHS Act (79 FR 69601). The proposed rule in § 11.10 adopted the definition of applicable drug clinical trial in section 402(j)(1)(A)(iii)(I) of the PHS Act and further clarified that, as specified in sections 402(j)(1)(A)(iii)(II) and (III), the term "clinical investigation" has the meaning given in 21 CFR 312.3 (or any successor regulation) and "phase I" has the meaning given in 21 CFR 312.21 (or any successor regulation). We did, however, propose to replace "phase I" with "phase 1," to be consistent with the numbering scheme used in FDA regulations (21 CFR 312.21). We provided additional elaboration of the interpretation of the term "applicable drug clinical trial" in the NPRM (79 FR 69601).

In addition, for the purposes of implementing the rule, we proposed to treat certain clinical trials of combination products as applicable drug clinical trials. Combination products are defined in 21 CFR 3.2(e). A combination product is comprised of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, a biological product, and a device that, for example, are physically, chemically, or otherwise combined or mixed and produced as a single entity or are separate products packaged together in a single package or as a unit (see 21 CFR 3.2(e)(1) and (2)). Because the definition of a "drug" in proposed § 11.10 included a biological product, we stated in the proposed rule that a combination product would always consist, in part, of a drug. Therefore, we proposed to treat clinical trials of combination products that meet the definition in 21 CFR 3.2(e) as applicable drug clinical trials, for the purposes of the rule, as long as the clinical trial of the combination product is a controlled clinical investigation, other than a phase 1 clinical investigation, and the combination product is subject to sections 505 of the FD&C Act and/or section 351 of the PHS Act and/or section 510(k), 515, or 520(m) of the FD&C Act.

Several commenters addressed the proposed definition. Many commenters requested that the definition of "applicable drug clinical trial" include "phase 0" or phase 1 studies. One commenter requested that the definition include all interventional drug clinical trials, including phases 1–4, consistent with the EU Clinical Trial Registration requirements. Several commenters requested that the applicable drug clinical trial definition be expanded to include any trials in which a drug is introduced into the human body, but they agreed that the definition should not include observational studies. One commenter, as noted in the discussion of an applicable device clinical trial, opposed considering packaging or labeling in the United States as "manufacture[d] in the U.S." and requested clarification in the final rule. Another commenter requested that the rule clarify whether foreign trials not conducted under an IND with a drug product not exported from the United States, but which are subsequently included as a pivotal trial in a new drug application (NDA) or biologics license application (BLA), should be considered applicable clinical trials and therefore listed in Item 10 of Form FDA 3674.

Section 402(j)(1)(A)(iii)(I) of the PHS Act explicitly requires that the drug must be subject to section 505 of the FD&C Act or section 351 of the PHS Act and explicitly exempts phase 1 studies from the definition of "applicable drug clinical trial" and, therefore, from the registration and results information submission requirements. With respect to the comment regarding packaging or labeling, pursuant to section 510 of the FD&C Act, FDA's jurisdiction extends to the "manufacture, preparation, propagation, compounding or processing" of drugs, which term is defined to include "repackaging or otherwise changing the container, wrapper, or labeling or any drug package . . . in furtherance of the distribution of the drug . . . from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." The NPRM used the term "manufacture" as short-hand for all drug activities within FDA's jurisdiction. Therefore, a drug product that is packaged and/or labeled in the United States would be considered "manufactured" in the United States subject to section 505 of the FD&C Act or section 351 of the PHS Act. With respect to the question about a foreign trial, the issue of which trials should be listed on Form FDA 3674 is outside the scope of this rulemaking.

Commenters requested that we change the interpretation of the terms "applicable drug clinical trial" and "applicable device clinical trial" for combination products. The commenters asked that we rely on the "primary mode of action" (see 21 CFR 3.2(m)) to determine whether a combination product is an applicable drug clinical trial or applicable device clinical trial. We agree with these commenters and have modified the regulations to incorporate this change. FDA regulations in 21 CFR part 3 specify that the primary mode of action of a combination product is the single mode of action that provides the most important therapeutic action of the intended therapeutic effects of the combination product. A combination product with a device primary mode of action under 21 CFR part 3 would be considered an applicable device clinical trial, provided that it meets all other criteria of the definition under this part. A combination product with a drug primary mode of action under 21 CFR part 3 would be considered an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part.

In § 11.10(a) of the final rule, we define "applicable drug clinical trial" to mean a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the FD&C Act (21 U.S.C. 355) or a biological product subject to section 351 of the PHS Act (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 and "phase 1" has the meaning given in 21 CFR 312.21. In addition, a clinical trial of a combination product, where the combination product meets the definition in 21 CFR 3.2(e) and has a drug primary mode of action under 21 CFR part 3 will be considered an applicable drug clinical trial, as long as the clinical trial of the combination product is a controlled clinical investigation, other than a phase 1 clinical investigation, and the combination product is subject to section 505 of the FD&C Act and/or section 351 of the PHS Act.

We interpret the definition of applicable drug clinical trial under section 402(j)(1)(A)(iii) of the PHS Act as having four operative elements: (1) "Controlled"; (2) "clinical investigation"; (3) "other than a phase [1] clinical investigation"; and (4) "drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of th[e] [Public Health Service] Act." A clinical investigation that meets all four elements is considered an applicable drug clinical trial. Conversely, a clinical investigation that does not meet one or more of these criteria would not be considered an applicable drug clinical trial. We have carefully considered these four criteria, and our interpretation follows in an order that facilitates the explanation.

(1) With regard to a "drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of th[e] [Public Health Service] Act," § 11.10(a) adopts the definition of the term "drug" in section 402(j)(1)(A)(vii) of the PHS Act as follows: "a drug as defined in section 201(g) of the [FD&C Act] or a biological product as defined in section 351 of th[e] [PHS Act]." Section 11.10(a) also clarifies in the definition of "applicable drug clinical trial" that the term "drug" refers to a particular manufacturer's drug product. In keeping with the requirements of the FD&C Act and section 351 of the PHS Act, a drug product or a biological product is considered to be "subject to section 505 of the [FD&C Act] or section 351 of th[e] [PHS Act]," as applicable, if it is the subject of an approved NDA or licensed BLA or if an approved NDA or licensed BLA would be required in order for that drug product or biological product to be legally marketed. A non-prescription drug product that is or could be marketed under an existing over-the-counter drug monograph (see 21 CFR 330–358) is not considered "subject to section 505 of the [FD&C Act]."

As discussed above, a clinical trial of a combination product with a drug primary mode of action under 21 CFR part 3 would be considered an applicable drug clinical trial, provided that it meets all other criteria of the definition under § 11.10(a).

A drug product or a biological product that is subject to section 505 of the FD&C Act or section 351 of the PHS Act and, therefore, would require an approved NDA or licensed BLA in order to be marketed legally can be shipped for the purpose of conducting a clinical investigation of that product if an IND is in effect. Drug products (including biological products) that are being studied under an IND are considered "subject to section 505 of the FD&C Act" both because (in most situations) the drug product being studied would need an approved NDA or licensed BLA to be marketed legally, and because INDs are issued by FDA pursuant to the authority in section 505(i) of the FD&C Act. We note that a substance characterized by a responsible party as a dietary supplement could be considered a "drug" subject to section 505 of the FD&C Act under the applicable drug clinical trial definition if the trial is studying a use that meets the drug definition under the FD&C Act. Furthermore, whether a drug product or biological product is subject to section 505 of the FD&C Act or section 351 of the PHS Act is a different question from whether a clinical investigator would need to obtain an IND from FDA before beginning to enroll human subjects in a clinical investigation. Therefore, a drug product or biological product being studied in a clinical investigation can be subject to section 505 of the FD&C Act or section 351 of the PHS Act, even if a clinical investigation of that drug product or biological product is "IND exempt" (*i.e.,* does not require an IND because that clinical investigation falls within 21 CFR 312.2(b)). Therefore, provided it meets all other criteria of the definition, a clinical investigation of a drug product (including a biological product) can be an applicable drug clinical trial under section 402(j) of the PHS Act and this part, even if it does not require an IND. Furthermore, if a sponsor chooses to obtain an IND (issued under section 505 of the FD&C Act) for a clinical investigation of a drug product (including a biological product) that is not otherwise subject to section 505 of the FD&C Act or section 351 of the PHS Act, the sponsor, in so doing, agrees to regulation under section 505 of the FD&C Act, and that clinical investigation thus will be considered an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part.

If a clinical investigation of a drug product (including a biological product) includes sites both within the United States (including any U.S. territory) and outside of the United States, and any of those sites is using (for the purposes of the clinical investigation) a drug product or biological product that is subject to section 505 of the FD&C Act or section 351 of the PHS Act, we would consider the entire clinical investigation to be an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part. However, a clinical investigation of a drug product (including a biological product) that is being conducted entirely outside of the United States (*i.e.,* does not have any sites in the United States or in any U.S. territory) may not be a clinical investigation of a drug product or biological product subject to section 505 of the FD&C Act or section 351 of the PHS Act, and therefore not an applicable drug clinical trial, depending on where the drug product (including biological product) being used in the clinical investigation is manufactured. If the drug product (including a biological product) is manufactured in the United States or any U.S. territory, and is exported for study in another country under an IND (whether pursuant to 21 CFR 312.110 or section 802 of the FD&C Act), the drug product or biological product is considered to be subject to section 505 of the FD&C Act or section 351 of the PHS Act (as applicable), and the clinical investigation may be an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part. If the drug product (including a biological product) is manufactured outside of the United States or its territories, the clinical investigation sites are all outside of the United States, and the clinical investigation is not being conducted under an IND, the drug product or biological product would not be considered to be subject to section 505 of the FD&C Act or section 351 of the PHS Act, and the clinical investigation would not be an applicable drug clinical trial. A drug product that is packaged and/or labeled in the United States would be considered "manufactured" in the United States subject to section 505 of the FD&C Act or section 351 of the PHS Act.

(2) With regard to "clinical investigation," section 402(j)(1)(A)(iii)(II) of the PHS Act provides that the term "clinical investigation" has the meaning given to it in 21 CFR 312.3, which defines a "[c]linical investigation" as "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects." The regulation further defines an "experiment" as "any use of a drug except for the use of a marketed drug in the course of medical practice."

The FDA definition of a "clinical investigation" of a drug includes studies in which human subjects are assigned to specific interventions according to a research protocol. However, a situation in which a drug product is administered or provided to a patient as part of routine medical care and not under a study or research protocol is not considered a clinical investigation for the purposes of this rulemaking. A clinical investigation does not include situations in which, after a drug product has been administered to patients in the course of routine medical practice by a healthcare provider, a researcher not associated with the administration of the drug product reviews the patients' records to assess certain effects, interviews the patients to assess certain impacts, or collects longitudinal data to track health outcomes. Similarly, a situation in which a healthcare provider only observes and records the effects of the use of a marketed drug product in the course of his or her routine medical practice is not considered a clinical investigation under this definition. Because these activities are not considered clinical investigations under 21 CFR 312.3, they are not considered applicable drug clinical trials under section 402(j) of the PHS Act and this part. Accordingly, in the approach described in § 11.22(b)(2), we consider an interventional study (or investigation) of a drug product to be one of the criteria for determining an applicable drug clinical trial.

(3) With regard to "controlled," we consider a "controlled clinical investigation" to be one that is designed to permit a comparison of a test intervention with a control to provide a quantitative assessment of the effect of the drug product. The purpose of the control is to distinguish the effect of a drug product from other influences, such as spontaneous change in the course of diseases, the placebo effect, or biased observation. The control will provide data on what happens to human subjects who have not received the test intervention or who have received a different intervention. Generally, the types of controls that are used in clinical investigations are as follows: (1) Placebo concurrent control, (2) dose-comparison control, (3) no intervention concurrent control, (4) active intervention concurrent control, and (5) historical control (see 21 CFR 314.126(b)). As discussed further in the definition of "control or controlled," we are clarifying for the purpose of this part that all interventional studies, both single-armed and multi-armed, with a pre-specified outcome measure are considered to be controlled (*i.e.,* comparing an intervention against a control).

In our view, a clinical investigation designed to demonstrate that an investigational drug product is bioequivalent to a previously approved drug product, or to demonstrate comparative bioavailability of two products (such as for the purposes of submitting an abbreviated new drug application (ANDA) under 21 U.S.C. 355(j) or an NDA as described in 21 U.S.C. 355(b)(2)), is considered to be a controlled clinical investigation. In this case, the control generally is the previously approved drug product. However, as discussed below, a bioequivalence or comparative bioavailability study that falls within the scope of 21 CFR 320.24(b)(1), (2), or (3) shares many of the characteristics of a phase 1 study and is considered to be a phase 1 trial (and, therefore, not an applicable clinical trial) in this rule.

As discussed above, expanded access protocols under section 561 of the FD&C Act do not fall within the definition of "applicable drug clinical trial."

(4) With regard to the "other than a phase [1] clinical investigation" element, an applicable drug clinical trial is defined in section 402(j)(1)(A)(iii) of the PHS Act to exclude phase 1 clinical investigations, consistent with 21 CFR 312.21. Under 21 CFR 312.21(a)(1), a phase 1 study "includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be

conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, phase 2 studies. The total number of subjects and patients included in phase 1 studies varies with the drug, but is generally in the range of 20 to 80.'' Under 21 CFR 312.21(a)(2), ''[p]hase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.'' Clinical trials that are phase 1 studies under 21 CFR 312.21 are not applicable drug clinical trials. Clinical trials that are identified as phase 1/phase 2 trials (*i.e.,* trials with characteristics of both phase 1 and phase 2 studies) are not considered phase 1 studies and may be applicable drug clinical trials if they meet the other specified criteria.

Under certain circumstances, a clinical investigation designed to demonstrate that an investigational drug product is bioequivalent to a previously approved drug product, or to demonstrate comparative bioavailability of two products (such as for the purposes of submitting an ANDA under 21 U.S.C. 355(j) or an NDA as described in 21 U.S.C. 355(b)(2)) will be considered to be a phase 1 clinical investigation under 21 CFR 312.21 for the purposes of determining whether a particular clinical trial is an applicable drug clinical trial under section 402(j)(1)(A)(iii) of the PHS Act. Although phase 1 clinical investigations are generally designed to fit sequentially within the development plan for a particular drug product, and to develop the data that will support beginning phase 2 clinical investigations, 21 CFR 312.21(a) does not limit phase 1 clinical investigations to that situation. A bioequivalence or comparative bioavailability study that falls within the scope of 21 CFR 320.24(b)(1), (2), or (3) shares many of the characteristics of a phase 1 clinical investigation as described in 21 CFR 312.21(a), and, therefore, is considered to be a phase 1 clinical investigation for the purposes of section 402(j) of the PHS Act (including in this rule). However, a bioequivalence or comparative bioavailability clinical trial that falls within the scope of 21 CFR 320.24(b)(4) does not share the characteristics of a phase 1 clinical trial as described in 21 CFR 312.21(a), and, therefore, is not considered to be a phase 1 clinical trial for the purposes of section 402(j) of the PHS Act (including in this rule).

Approved Drug

In the NPRM, we defined ''approved drug'' in proposed § 11.10(a) to mean ''a drug that is approved for any indication under section 505 of the Federal Food, Drug, and Cosmetic Act or a biological product licensed for any indication under section 351 of the Public Health Service Act'' (see 79 FR 69603). We received several comments on this proposed definition asserting that a clinical trial for a new use of an approved drug product would subject the clinical trial to the rule's requirements. We agree that clinical trials of new uses for an approved drug product can be subject to the rule, if the clinical trial also meets the definition of an ''applicable drug clinical trial'' and meets the requirements of § 11.22.

In the final rule, we maintain the definition except the final rule definition uses the term ''use'' instead of ''indication'' for further clarity. As explained elsewhere, for the purposes of this rule only, we interpret ''use'' to include ''indication.'' We also clarified in the final rule that ''drug'' refers to a particular manufacturer's drug product. We also include the applicable U.S.C. statutory citations in the definition. Based on our experience with *ClinicalTrials.gov* and routine queries from users, we are also clarifying two issues here. First, a drug product that is not approved for any use but is ''tentatively approved'' by FDA, as described in sections 505(j)(5)(B)(iv)(II)(dd)(AA) and (BB) of the FD&C Act, is not considered to be an approved drug for the purposes of section 402(j) of the PHS Act, and therefore is not included in the rule's definition of ''approved drug.'' Second, a drug product approved by FDA but for which approval is later withdrawn under section 505(e) of the FD&C Act, and that is no longer approved for any use, is not considered an approved drug for purposes of this part.

Approved or Cleared Device

In the NPRM, we defined ''approved or cleared device'' in § 11.10(a) to mean ''a device that is cleared for any indication under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved for any indication under sections 515 or 520(m) of that Act.'' As we explained, section 402(j)(2)(D)(ii)(II) of the PHS Act uses the phrase ''a device that was previously cleared or approved'' to refer to a subset of devices that, if studied in an applicable device clinical trial, would trigger certain requirements under this proposed part with respect to the public posting of clinical trial information (79 FR 69603). Accordingly, we proposed defining the term ''approved or cleared device'' to refer to any device that has been approved or cleared under the applicable section of the FD&C Act for any indication, even if the applicable device clinical trial studies the device for an unapproved or uncleared use. We received several comments on this definition asserting that a clinical trial for a new use of an approved or cleared device would subject the clinical trial to the rule's requirements. We agree that clinical trials of new uses for an approved or cleared device can be subject to the rule, if the clinical trial also satisfies the ''applicable device clinical trial'' definition elements and other triggering requirements, such as § 11.22 for registration.

The final rule maintains the definition, except that the final rule definition uses the term ''use'' instead of ''indication'' for further clarity. As explained elsewhere, for the purposes of this rule only, we interpret ''use'' to include ''indication.'' We also clarified that the term ''device'' refers to a particular manufacturer's device product and include the applicable U.S.C. statutory citations in the definition.

Arm

In the NPRM, we defined ''arm'' in § 11.10(a) to mean ''a pre-specified group or subgroup of human subjects in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.'' We received no comments on this definition, and we maintain the definition in the final rule, except the final rule definition modifies the phrase ''human subjects'' to ''human subject(s)'' for further clarity.

Clinical Study

The NPRM did not propose a definition of ''clinical study'' in § 11.10(a) but we are including the term and data element in this final rule. The term ''clinical study'' is used in the statutory definition of ''applicable device clinical trial'' (see section 402((j)(1)(A)(ii)(I) of the PHS Act), and the NPRM discussed ''clinical study'' in the context of this definition (79 FR 69599). ''Clinical study'' is also used in the definition of ''clinical trial'' in § 11.10(a) of this regulation. To provide further clarity, we define the term "clinical study" in § 11.10(a) to mean "research according to a protocol involving one or more human subjects to evaluate biomedical or health-related outcomes, including interventional studies and observational studies." This definition is consistent with our discussion of the term's meaning in the NPRM (79 FR 69599).

Clinical Trial

In the NPRM, we defined "clinical trial" in § 11.10(a) to mean "a clinical investigation or a clinical study in which human subjects are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effects of the interventions on biomedical or health-related outcomes." As we explained, the definition explicitly included biomedical in addition to health-related outcomes because we have defined the term "clinical trial" to include phase 1 studies, which may measure physiological changes that are biomedical in nature but may not be related to health effects (79 FR 69603). We defined the term "clinical trial" to include phase 1 studies, in part, because phase 1 studies may be voluntarily submitted under section 402(j)(4)(A) of the PHS Act. The restriction of the scope of this definition to clinical investigations or studies in which human subjects are prospectively assigned to interventions was intended to distinguish clinical trials (interventional studies) from observational studies, in which the investigator does not assign human subjects to interventions, but, for example, observes patients who have been given interventions in the course of routine clinical care. Observational studies may also include retrospective reviews of patient medical records or relevant literature.

Several commenters addressed the proposed definition. Many commenters requested that we define "clinical trial" to mean any trial in which a drug, biologic, device, radioactive material, or any other foreign body is introduced into the human body. We do not use this alternative definition because it includes the use of drugs, biologics, devices, or radioactive materials provided to a patient as part of routine medical care, such as in observational studies. Other commenters requested that we resolve any differences between the proposed rule's definition and the definitions of "clinical trial" used by NIH and ICMJE, and the definition of "qualified clinical trial" used by the Centers for Medicare & Medicaid Services. These commenters expressed concern that any differences in definitions could lead to inconsistencies in how responsible parties must register and report results information across these contexts. We note that the definition of "clinical trial" we proposed is consistent with the NIH, ICMJE, and WHO definitions, although the scope of what needs to be registered differs from other contexts because of the requirements of section 402(j) of the PHS Act. We note that the *ClinicalTrials.gov* system allows for the reporting of studies that are not subject to (or are independent of) requirements under section 402(j) of the PHS Act, including under different timelines and with additional information, which means that reporting in these other contexts is not impeded. Finally, the proposed definition of "clinical trial" did not distinguish between approved, licensed, or cleared uses and unapproved, unlicensed, or uncleared uses, and therefore human testing of an approved drug or device for a new use can fall within the scope of a clinical trial. These clinical trials, though, must meet the definition of an "applicable clinical trial" and other conditions of the regulation in order for registration and results information reporting to be required under section 402(j) of the PHS Act.

In the final rule, we maintain the proposed definition for "clinical trial," except the final rule definition modifies the phrase "human subjects" to "human subject(s)" for further clarity. In terms of defining the scope of a clinical trial, we recognize that it may sometimes be difficult to determine whether two or more closely related studies should be considered a single clinical trial for the purposes of this part. In general, a clinical trial has a defined group of human subjects who are assigned to interventions, and the collected data are assessed and analyzed, based on a protocol. However, when two different studies use the same protocol but involve different groups of human subjects, and the plan is to analyze the data from the two studies separately, the two studies should be considered separate clinical trials. This is distinct from a situation in which multiple sites of the same clinical trial follow the same protocol with different groups of human subjects, but the intention is to analyze the primary outcome measure(s) with pooled data from all the study sites. Additionally, when some (or all) human subjects from a clinical trial are offered the opportunity to participate in an additional clinical trial that was not part of the original protocol (*e.g.,* a follow-on study), and participation requires a separate consent process, the additional clinical trial would generally be considered a separate clinical trial.

Clinical Trial Information

In the NPRM, we defined "clinical trial information" in § 11.10(a) to mean "the data elements, including clinical trial registration information and clinical trial results information, the responsible party is required to submit to *ClinicalTrials.gov* under this part." As we explained, section 402(j)(1)(A)(iv) of the PHS Act expressly provides that "[c]linical trial information" means "those data elements that the responsible party is required to submit under paragraph (2) or under paragraph (3)" of section 402(j) of the PHS Act (79 FR 69603). Paragraph (2) refers to registration requirements, including the registration information that is included in proposed § 11.28, and paragraph (3) refers to results information submission requirements, including results information in proposed § 11.48. Section 402(j)(3)(I)(v) of the PHS Act also expressly provides that adverse event information included in the data bank pursuant to paragraph (3)(I) "is deemed to be clinical trial information included in such data bank pursuant to subparagraph (C)."

We received no comments on this definition. We are clarifying on our own initiative that clinical trial information is submitted to *ClinicalTrials.gov* as specified in section 402(j) of the PHS Act and as specified in the final regulations; we also corrected a typographical error. Therefore, for the purposes of the final rule, clinical trial information means "the data elements, including clinical trial registration information and clinical trial results information, that the responsible party is required to submit to *ClinicalTrials.gov*, as specified in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) and this part."

Clinical Trial Registration Information

In the NPRM, we defined "clinical trial registration information" in § 11.10(a) to mean "the data elements that the responsible party is required to submit to *ClinicalTrials.gov*, as listed under § 11.28." We received no comments on this definition. We clarify that the full set of data elements specified in § 11.28 must be submitted in order to register an applicable clinical trial for applicable clinical trials with an initiation date on or after the effective date of the final rule, as discussed further in section IV.F. Effective Date, Compliance Date, and Applicability of Requirements in this part. For applicable clinical trials with an initiation date before the effective date of the final rule, clinical trial registration information must be submitted as specified in section 402(j)(2)(A)(ii) of the PHS Act. Therefore, for the purposes of the final rule, clinical trial registration information means "the data elements that the responsible party is required to submit to *ClinicalTrials.gov,* as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) or § 11.28, as applicable."

Clinical Trial Results Information

In the NPRM, we defined "clinical trial results information" in § 11.10(a) to mean "the data elements that the responsible party is required to submit to *ClinicalTrials.gov* under § 11.48 or, if applicable, § 11.60(a)(2)(i)(B)." We noted that clinical trial results information includes the adverse event information set forth in proposed § 11.48(a)(4) pursuant to section 402(j)(3)(I)(v) of the PHS Act, which indicates that the adverse event information included in the registry and results data bank under section 402(j)(3)(I) of the PHS Act "is deemed to be clinical trial information included in [the] data bank pursuant to [section 402(j)(3)(C) of the PHS Act]" (79 FR 69603). We received no comments on this definition.

We clarify in the final rule that the full set of data elements under § 11.48 must be submitted when results information is submitted for applicable clinical trials with a primary completion date on or after the effective date of the final rule, as discussed further in section IV.F. Effective Date, Compliance Date, and Applicability of Requirements in this part. For applicable clinical trials with a primary completion date before the effective date of the final rule, results information must be submitted as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act. We also note that, under § 11.60, if a responsible party seeks to submit clinical trial results information voluntarily for an applicable clinical trial with a primary completion date on or after the effective date and for which clinical trial registration information is not submitted, clinical trial results information is defined to include the data elements in § 11.48 and the data elements in § 11.60(b)(2)(i)(B) or (c)(2)(i)(B), as applicable. Therefore, for the purposes of the final rule, "clinical trial results information" means "the data elements that the responsible party is required to submit to *ClinicalTrials.gov,* as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and (I)) or § 11.48, as applicable. If a responsible party submits clinical trial results information voluntarily for a clinical trial, clinical trial results information also means § 11.60(b)(2)(i)(B) or § 11.60(c)(2)(i)(B), as applicable."

Comparison Group

In the NPRM, we defined "comparison group" in proposed § 11.10(a) to mean "a grouping of human subjects in a clinical trial, other than an arm, that is used in analyzing the results data collected during the clinical trial" (see 79 FR 69604). We received no comments on this definition and maintain the definition in the final rule, except the final rule definition clarifies that the grouping "is or may be" used in analyzing the results data.

We clarify that, in some trials, results data are not analyzed according to the arms to which human subjects were assigned; the data may be combined into other groupings for analysis. For example, in a cross-over study, human subjects in one arm of a trial may receive intervention X for a period of time followed by intervention Y, while human subjects in another arm of the trial may receive intervention Y for a period of time followed by intervention X. In such studies, outcome measures and adverse events are often analyzed and reported by intervention (*e.g.,* results for human subjects when receiving intervention X versus results for human subjects when receiving intervention Y), rather than by arm.[Ref. 84] When submitting results information to *ClinicalTrials.gov* under § 11.48, responsible parties must submit data in the way in which they were analyzed, whether by arm (as defined above) or by comparison group. We note that, in general, the set of comparison groups for a particular trial should account for all of the participants in the analysis.

Completion Date

In the NPRM, we defined "completion date" in § 11.10(a) to mean "for a clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. In the case of clinical trials with more than one primary outcome measure with different completion dates, this term refers to the date upon which data collection is completed for all of the primary outcomes."

As we explained in the NPRM, "completion date" is defined in section 402(j)(1)(A)(v) of the PHS Act as "the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated" (79 FR 69604). This term has particular significance because the responsible party is required to submit "the expected completion date" to *ClinicalTrials.gov* upon registration (see section 402(j)(2)(A)(ii)(I)(jj) of the PHS Act) and submit clinical trial results information for certain applicable clinical trials not later than 1 year after the earlier of the estimated or the actual completion date (see sections 402(j)(3)(E)(i)(I) and (II) of the PHS Act), unless the deadline is delayed or extended using one of the mechanisms described in § 11.44. For purposes of the proposed rule, we interpreted "expected completion date" in section 402(j)(2)(A)(ii)(I)(jj) of the PHS Act to be synonymous with "estimated completion date" in section 402(j)(3)(E)(i)(I) of the PHS Act.

The proposed rule adopted the statutory definition of "completion date" with respect to applicable clinical trials but proposed one modification. For a clinical trial that has multiple primary outcome measures each with a different date on which the final human subject is examined or receives an intervention for the purposes of final data collection, we proposed that "completion date" would refer to the date on which data collection is completed for all of the primary outcomes. The proposed rule also defined "completion date" for a pediatric postmarket surveillance of a device that is not a clinical trial as "the date on which the final report summarizing the results of the pediatric postmarket surveillance is submitted to FDA." The proposed rule also noted that the current implementation of *ClinicalTrials.gov* uses the term "primary completion date" to refer to "completion date," as defined in section 402(j)(1)(A)(v) of the PHS Act. This was done in the data bank to alert those submitting data to *ClinicalTrials.gov* under section 402(j) of the PHS Act that the definition of "completion date" differs from that of the term "study completion date," which refers to the date on which the last subject makes the last visit as part of the clinical trial (commonly referred to as Last Patient Last Visit (LPLV)) and is also collected by *ClinicalTrials.gov* as an optional data element [Ref. 85]. We stated that

ClinicalTrials.gov would begin to use the term "completion date" once the final regulations take effect and that we would include a notice on *ClinicalTrials.gov* to alert responsible parties to this change in data element name.

We received comments on this definition. Commenters expressed concern about confusion and possible misinterpretation among responsible parties and the public about the definition. Many of these commenters suggested replacing "completion date" with "primary completion date" or "primary outcome measure completion date," noting that *ClinicalTrials.gov* has used "primary completion date" since the enactment of FDAAA. Several other commenters requested that "completion date" be redefined to mean LPLV. In addition, several commenters supported the NPRM position that when there are multiple primary outcome measures, the completion date is interpreted as "the date upon which data collection is completed for all of the primary outcomes." Two commenters also requested further clarification in the definition about the term's application to trials that are terminated, particularly when the decision to terminate occurs more than 1 year after the last previously enrolled subject reached the data collection point for a primary outcome measure, but before the enrollment goals are reached. One commenter requested clarification regarding cases in which sample analysis occurs after a patient's last visit. We did not receive any comments on the definition of "completion date" for a pediatric postmarket surveillance of a device that is not a clinical trial.

We generally maintain the definition of "completion date" in § 11.10(a) in the final rule because the statute explicitly defines the term in this way. We have made a minor modification, consistent with the statutory definition, to clarify that the term "clinical trial" includes an applicable clinical trial; we have also clarified that "device" means "device product." However, we agree with the comments, so we are clarifying that "completion date" is synonymous with "primary completion date," to avoid confusion among researchers and the public. We have revised the definition of "completion date" to state that for purposes of this part, the term "completion date" is referred to as "primary completion date." We use the term "primary completion date" in this preamble and in the codified provisions. We also add to final § 11.10(a) the term "primary completion date," which is defined as and refers to the definition of "completion date." In addition, *ClinicalTrials.gov* will continue to use the term "primary completion date" and the related data element to refer to "completion date," as defined in § 11.10(a) of the final rule. We believe that this approach balances the need to implement terms that are specifically defined by section 402(j) of the PHS Act while being responsive to commenters' concerns that the statutory definition of "completion date" differs from the way the term is commonly used by the clinical research community. This change will also help clarify the meaning of the statutory term for users.

Also, with regard to comments suggesting that "completion date" should mean LPLV, we note that adopting such an approach would be inconsistent with the statutory definition. However, we do add the Study Completion Date data element, which is currently an optional data element in *ClinicalTrials.gov*, as a required component of clinical trial registration information in the final rule, and we include a definition of "study completion date" in § 11.10(a). (See also the discussion of "study completion date" later in this preamble.) As supported by the commenters, we also maintain the definitional element for multiple primary outcomes as proposed, *i.e.*, that "completion date" (and "primary completion date") means the date on which data collection is completed for all of the primary outcomes. As explained in the NPRM, while this approach may delay the submission and public availability of clinical trial results information for the earliest primary outcomes, we expect any such delays to be minimal (79 FR 69604). Most clinical trials registered on *ClinicalTrials.gov* to date specify only a single primary outcome, and those with multiple primary outcomes have measurement time frames that are relatively close in time.

Moreover, this approach avoids cases in which the submission of clinical trial results information would be required before data collection has been completed for all of the primary outcomes in a clinical trial and before all of the results data for the primary outcomes have been "unblinded," a situation that could threaten the scientific integrity of the clinical trial. While a responsible party could request a good-cause extension of the results information submission deadline in such a situation under § 11.44(e), the definition in the final rule should reduce the number of good-cause extension requests that responsible parties might be expected to file. Submission of results information for all primary outcomes at the same time will also aid in the interpretation of clinical trial results information by providing users of *ClinicalTrials.gov* with a more comprehensive set of results information from the clinical trial, rather than results information for only some of the primary outcomes.

In response to the commenters seeking clarification about the completion date for terminated clinical trials, we do not believe that any changes to the definition are needed. Under the definition of "completion date," the completion date of a terminated trial is the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, which may be on or before the trial termination. By "final subject," the definition means the last subject who was examined or received an intervention before the trial was terminated. We do not interpret this definition as meaning that all enrolled subjects must be examined or receive an intervention before the clinical trial is terminated in order for the trial to reach the completion date. As described in the discussion of § 11.48 in this preamble, the responsible party would provide the clinical trial results information that had been collected for those subjects who were examined or received the intervention up to the point of termination. In response to one commenter, we clarify that if an applicable clinical trial is terminated on a date that is after the last subject was examined or received an intervention for a primary outcome measure, the completion date would still be the date that the final subject was examined or received an intervention for the primary outcome before trial termination, regardless of when the decision to terminate was made and whether the enrollment goals were reached. In this scenario, it is possible that the decision to terminate the trial could occur after the standard submission deadline for study results information under § 11.44(a) (*i.e.*, 1 year after the primary completion date) or may occur during a period that is much less than 1 year after the primary completion date. We clarify that upon trial termination, a responsible party may submit a request demonstrating good-cause for extending the results information submission deadline as specified in § 11.44(e). Finally, in response to another comment, we do not agree that the date of sample analysis after a subject's last examination or receipt of the intervention should qualify as the "completion date" under the definition. We view sample analysis as a separate step from data collection; moreover, including it in the definition of "completion date" would be inconsistent with the statutory definition. We also note that an analysis could be conducted months or even years after the last subject was examined or received an intervention, which could significantly delay the reporting of results information under § 11.44. We clarify that if there are extenuating circumstances that cause a delay in sample analysis that interferes with meeting the results information submission deadline specified in § 11.44, the responsible party may submit a request for extending the results information submission deadline as specified in § 11.44(e).

In § 11.10(a) of the final rule, we define "completion date" to mean "for a clinical trial, including an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. In the case of clinical trials with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes. For a pediatric postmarket surveillance of a device product that is not a clinical trial, completion date means the date on which the final report of the pediatric postmarket surveillance of the device product is submitted to FDA. For purposes of this part, completion date is referred to as 'primary completion date.'"

Control or Controlled

In the NPRM, we defined "control or controlled" in § 11.10(a) to mean "with respect to a clinical trial, that data collected on human subjects in the clinical trial will be compared to concurrently collected data or to non-concurrently collected data (*e.g.*, historical controls, including a human subject's baseline data), as reflected in the pre-specified primary or secondary outcome measures." "Control" and "controlled" are terms used in sections 402(j)(1)(A)(ii)(I) and (iii)(I) of the PHS Act as part of the definitions of "applicable device clinical trial" and "applicable drug clinical trial," respectively. As we explained in the NPRM, the definition is consistent with (but broader than) FDA regulations that define the related concepts of "adequate and well-controlled studies" for drugs (21 CFR 314.126(b)(1) and (2)) and "a well-controlled clinical investigation" for devices (21 CFR 860.7(f)) (79 FR 69604). FDA has also adopted as guidance the ICH E10: Choice of Control Group and Related Issues in Clinical Trials, which describes considerations to be used in choosing a control group [Ref. 86]. In FDA regulations, the critical attribute of a well-controlled clinical trial, which is the intent of any controlled trial, is "a design that permits a valid comparison with a control to provide a quantitative assessment" of the effect of the investigational intervention (see 21 CFR 314.126(b)(2)). The FDA regulations recognize several types of concurrent controls (*e.g.*, active control) and the non-concurrent, historical control. This can refer to a control group for which data were collected at a different time or place but can also refer to a clinical trial in which subjects serve as their own controls (*e.g.*, the clinical trial measures change from baseline).

We explained in the NPRM that, for purposes of determining whether it is an applicable clinical trial subject to this part, the proposed definition of "control or controlled" would include any clinical trial with multiple concurrent arms (79 FR 69574 and 69605). In addition, we explained that some single-arm clinical trials would also be included in the definition. Such trials would include single-arm trials of FDA-regulated products that, as specified in their protocols, intend to evaluate an effect by comparing measures taken after an intervention to baseline measures taken from the participants prior to the intervention. Many of these studies have explicitly defined "change from baseline" measures identified in their protocols, *i.e.*, they are designed to compare a measure taken after an intervention to the participant's state prior to the intervention. Other single-arm trials that would be considered controlled include, for example, studies with an identified measure of "response rate" or measures in which the state prior to or without the intervention can be assumed (*e.g.*, studies in conditions that do not resolve over the time period studied without the intervention, such as certain types of cancer).

We proposed in § 11.10(b)(5) that the Study Design data element include, for single-armed studies, whether or not the clinical trial is controlled, as specified by the protocol or SAP. Accordingly, proposed § 11.28(a)(i)(v) would require that a responsible party that registers a single-arm trial provide this information. We also proposed in § 11.22(b) that a trial or study that was described accurately by the data elements listed in § 11.22(b)(1) or (2) would be considered to meet the definition of an applicable clinical trial. We invited comments on the proposed approach for identifying single-arm trials that would be considered controlled and on alternative ways to identify such trials (79 FR 69574). In particular, we invited comments on whether there are other specific, objective features of clinical trials that could serve as the basis for differentiating between single-arm studies that are and are not controlled. We also invited comments on and information about the types of single-arm trials that meet the other criteria for an applicable clinical trial and do or do not meet our proposed definition of "controlled."

We received several comments on the definition. One commenter supported the proposed definition, particularly including single-arm studies. Several commenters sought clarifications of the definition. Some commenters stated that *all* interventional studies in humans should be considered controlled for the purposes of the NPRM, including single-arm studies. Some commenters indicated that ambiguity around the definition of controlled could result in responsible parties making erroneous, subjective assessments and failing to register or submit information for certain trials. One of these commenters suggested that if the definition was not clarified to include all interventional studies, the rule should require a responsible party registering a single-arm study without a control to explain the trial's purpose, ethical approval, justification for the lack of a control, and knowledge to be obtained. Another commenter requested that the final rule amend the definition of "controlled" to include single-arm studies assessing changes from historical controls or baseline or, alternatively, revise the definition to clarify that all single-arm trials are considered controlled. Two commenters indicated that all single-arm interventional studies should be considered controlled by asserting that all such studies that otherwise meet the definitional criteria specified in proposed § 11.22(b) are considered to be applicable clinical trials. One of these commenters emphasized that single-arm studies should be considered controlled because they compare collected data to other information (*e.g.*, participant baseline data); the other commenter objected that the NPRM's proposal to distinguish controlled clinical trials from other trials is potentially confusing—especially in light of FDA's regulatory definition of "[adequate and] well-controlled" trials, and asserted that the "controlled" definition was unnecessary for the applicable clinical trial determination. The commenter also noted that removing the "controlled" criterion and requiring results information reporting for all trials would better align the rule to the EU Clinical Trials Regulation. Finally, several commenters stated that no control groups should be allowed in clinical trials involving life-threatening conditions.

Other commenters asserted that the current definition of "control or controlled" is too broad. One stated that only multi-armed studies are controlled and that the standard use of the term "controlled" in the scientific community worldwide includes a comparison group. The commenter requested that for any single arm studies to be defined as controlled, a separate proposed rule with this approach should be issued for comment. Two commenters also expressed concerns that the meaning of "controlled" in the NPRM's definition differed from the FDA's definition of "adequate and well controlled," and one suggested harmonizing the final rule with the EU Clinical Trials Regulation requirements for results information reporting but limiting the scope to "adequate and well controlled" studies under 21 CFR 314.126.

Another commenter suggested that the proposed definition may be too broad and that it could conceivably encompass any interventional study in which patient data are captured at baseline and post-intervention. The commenter suggested that to be included in the definition, a single-arm trial would need to be able to plausibly distinguish the effect of an intervention from other causes and, furthermore, that the definition could be revised to be limited to trials "designed to permit a comparison of a test intervention with a control to provide a quantitative assessment of the effect of an intervention." The commenter also requested that NIH provide additional guidance for responsible parties on how to determine whether the study is controlled. Another commenter stated that single-arm phase 2 studies should be considered controlled only if they involve the comparison of primary and secondary endpoints and adverse events with a specific historical cohort. The commenter stated that a trial should not be considered controlled simply by the use of a pre-specified benchmark for the primary endpoint.

We have reconsidered our proposed approach based on the comments and determined that all interventional studies with pre-specified outcome measures should be considered controlled under the definition in the final rule, whether the trial has a single group of human subjects or involves two or more concurrent groups of human subjects. We agree with those comments suggesting that any single-arm interventional trial with pre-specified outcome measure(s) be considered controlled since it implicitly or explicitly compares the effect of the intervention to some other information (*e.g.*, patient baseline). Under our definition of "interventional," the effect of the intervention on biomedical or other health-related outcomes is evaluated according to a research protocol. In order to assess the effect of the experimental intervention, plans for single-arm trials identify how the outcomes will be measured. Either explicitly or implicitly, the measured outcomes are compared with either the patients themselves prior to the intervention or historical data from other patients (or subjects). Therefore, a single-arm interventional study with pre-specified outcome measure(s) would always involve the use of some type of control to evaluate the intervention's effect.

This revised approach simplifies the rule's application by making it clearer, less subjective, and easier for responsible parties to implement. For example, the revised approach eliminates the need for a responsible party to rely on a subjective determination of "controlled" for single-group studies. In addition, the approach minimizes the chances of an applicable clinical trial not being registered (and subsequently not reporting results information). The approach also harmonizes the definition of "control or controlled" for trials of drugs and device products. Importantly, we believe the approach supports the purpose of the provisions of section 402(j) of the PHS Act to make more information about clinical trials available to the public. Accordingly, § 11.10(a) of the final rule defines "control or controlled" to include not only concurrent control groups, but also non-concurrent controls, which would include all single-arm clinical trials with pre-specified outcome measures. In addition, the following clarification is added to the end of the definition: "For purposes of this part, all clinical trials with one or more arms and pre-specified outcome measure(s) are controlled." We wish to note, however, that although in certain circumstances some types of expanded access use under section 561 of the FD&C Act arguably might fall within this definition, as discussed above, expanded access use is not considered to fall within the definition of "applicable drug clinical trial."

The definition of "control or controlled" in the final rule is consistent with the types of controls recognized by FDA and the ICH E10 guidance (*i.e.*, recognition of both concurrent and non-concurrent controls) [Ref. 86]. The definition, however, is necessarily broader than the definition of "adequate and well-controlled" used in FDA regulations and the ICH E10 guidance because the purpose of this term, as used in this rule, is different from the more limited circumstances in which use of a non-concurrent control constitutes an "adequate and well-controlled" clinical trial, *i.e.*, one that might serve to support marketing authorization. Our definition does not reflect a consideration of the adequacy or appropriateness of the control or the adequacy of the study design, *e.g.*, whether adequate steps were taken to minimize bias. Because the transparency goals underlying this final rule also apply to clinical trials that may not be considered "adequate and well-controlled" under FDA regulations, we conclude that responsible parties are required to register and submit results information for such trials. Therefore, the definitions of "applicable device clinical trial" and "applicable drug clinical trial" include clinical trials with pre-specified outcome measures, whether using concurrent or non-concurrent controls, regardless of whether they would be considered "adequate and well-controlled."

Device

In the NPRM, we defined "device" in § 11.10(a) to mean "a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))" as specified in section 402(j)(1)(A)(vi) of the PHS Act (see 79 FR 69668). We received no comments on this definition, and we retain it without modification in the final rule.

Director

In the NPRM, we defined "Director" in § 11.10(a) to mean the NIH Director or any official of the NIH to whom the NIH Director delegates authorities granted in 42 U.S.C. 282(j) (see 79 FR 69668). We received no comments on this definition, and we maintain it in the final rule, except that we clarify the statutory reference as "section 402(j) of the Public Health Service Act (42 U.S.C. 282(j))."

Drug

In the NPRM, we defined "drug" in § 11.10(a) to mean "a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) or a biological product as defined in section 351 of the Public Health Service Act (42 U.S.C. 262)," as specified in section 402(j)(1)(A)(vii) of the PHS Act (see 79 FR 69668). We received no comments on this definition, and we retain it without modification in the final rule.

Enroll or Enrolled

In the NPRM, we defined "enroll or enrolled" in § 11.10(a) to mean "a human subject's agreement to participate in a clinical trial, as indicated by the signing of the informed consent document(s)." As we explained, "enroll or enrolled" is a term used in section 402(j)(1)(A)(viii)(I) of the PHS Act as part of the definition of "[o]ngoing" and in 402(j)(2)(C)(ii) of the PHS Act as one of the criteria used to establish the deadline by which a responsible party is required to submit clinical trial registration information (79 FR 69605).

We received comments on this definition. Several commenters asserted that the proposed definition of "enrolled" may be inconsistent with the way the term is used for presenting information about device studies in the Summary of Safety and Effectiveness or the 510(k) Summary, which are publicly available on FDA's Web site and to which *ClinicalTrials.gov* is required to link. The commenters stated that device trials can include subjects who, according to the trial design, provide consent for screening but enroll only those subjects who subsequently pass screening. The commenters asserted that the definition of "enrolled" proposed in the NPRM would require the inclusion of those subjects who provide consent for screening but do not pass screening, thereby resulting in an inconsistency in enrollment numbers reported on the *ClinicalTrials.gov* Web site and FDA's 510(k) Summary or Summary of Safety and Effectiveness, which would lead to confusion.

We acknowledge that there may be differences in the numbers of participants who sign an informed consent, are screened for participation, and are eligible to participate in the clinical trial. Therefore, we clarify that the definition of "enroll or enrolled" does not include "potential subjects who are screened for the purpose of determining eligibility for the trial but do not participate in the trial, unless otherwise specified by the protocol."

We note that, in some cases, there may be a separate informed consent document for trial screening and trial participation; the signing of the latter aligns with the proposed definition. We clarify that when there is only one informed consent for both trial screening and trial participation, and it is signed prior to participant screening, a participant is not considered enrolled until he or she has met all the eligibility criteria assessed during screening, unless the participant is considered enrolled specifically by the protocol. We clarify that for the purposes of the registration submission requirement in § 11.24, clinical trial registration information is required to be submitted no later than 21 calendar days after the first subject signs the informed consent form for trial participation. When there is only one informed consent for both trial screening and trial participation, we clarify that clinical trial registration information is required to be submitted pursuant to § 11.24 no later than 21 calendar days after the first subject signs the informed consent form and begins trial participation, in accordance with the protocol.

Commenters also stated that the definition of "enroll or enrolled" should be expanded to include "unless specifically defined differently in the protocol." The commenters asserted that not all studies consider the signing of informed consent to be the point of enrollment, and that the signing of informed consent may not be required. Moreover, based on these particular comments, we believe the wording of the proposed definition may inadvertently suggest that a written signature is the only acceptable confirmation of a subject's consent to participate. We have modified the definition to account for situations in which consent is provided by a subject's legally authorized representative (*e.g.,* a family member) because the subject is not able to provide informed consent because of, for example, mental incapacity. To address these and the previous comments, we are revising the definition of "enroll or enrolled" to mean "a human subject's, or their legally authorized representative's, agreement to participate in a clinical trial following completion of the informed consent process as required in 21 CFR part 50 and/or 45 CFR part 46, as applicable. For the purposes of this part, potential subjects who are screened for the purpose of determining eligibility for the trial, but do not participate in the trial, are not considered enrolled unless otherwise specified by the protocol."

Human Subjects Protection Review Board

In the NPRM, we defined "human subjects protection review board" in § 11.10 to mean an "institutional review board (IRB) as defined in 21 CFR 50.3 and 45 CFR 46.102 (or any successor regulation), as applicable, or equivalent independent ethics committee that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation and is adequately constituted to provide assurance of that protection." We proposed to include this definition to clarify the scope of the review boards for which Human Subjects Protection Review Board Status must be submitted under § 11.28 (79 FR 69605). We did not receive any comments on this definition, but for further clarity we are modifying the definition in the final rule to mean "an institutional review board (IRB) as defined in 21 CFR 50.3 or 45 CFR 46.102, as applicable, that is responsible for assuring the protection of the rights, safety, and well-being of human subjects involved in a clinical trial and is adequately constituted to provide assurance of that protection. An IRB may also be known as an 'independent ethics committee.'" For clinical trials conducted in the United States or under an IND or IDE, the term "human subjects protection review board" means an IRB, as defined in the cited regulations issued by FDA and HHS. For clinical trials conducted outside the United States or which are otherwise not subject to the FDA and/or HHS regulations for IRBs, the term refers to other independent ethics committees that are responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation and are adequately constituted to provide assurance of that protection. This phrasing is consistent with, but not identical to, the definition of the term "independent ethics committee" in FDA regulations for INDs (see 21 CFR 312.3). It is also consistent with longstanding use of the term "human subjects protection review board" on *ClinicalTrials.gov*, which instructed registrants to provide information about "[a]ppropriate review boards[, including] an Institutional Review Board, an ethics committee or an equivalent group that is responsible for review and monitoring of this protocol to protect the rights and welfare of human research subjects" [Ref. 85].

Interventional

In the NPRM, we defined "interventional" in § 11.10 to mean "with respect to a clinical study or a clinical investigation, that participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health related outcomes." The term "interventional" is used in § 11.22 as one of the elements (*i.e.,* interventional Study Type) used to determine whether a clinical study or a clinical investigation is an applicable clinical trial that is required to be registered. We proposed to define this term to distinguish interventional studies from observational studies, as those terms are used in the clinical research community (79 FR 69605). Observational studies consist of medical research in which the investigator does not assign human subjects to interventions. Observational studies include prospective cohort studies in which individuals received interventions as part of their medical care, after which the investigator studies prespecified outcomes to examine the impact of those interventions. Observational studies also include retrospective reviews of patient medical records or relevant literature. In contrast, in interventional studies, a researcher assigns subjects to specific interventions (*e.g.,* placebo, routine medical care, or no intervention) according to a study protocol for the purposes of the investigation. We explain in the preamble discussion for the definition of "protocol" in § 11.10(a) of the final rule that a less formal research plan would also be considered a protocol for the purposes of this part, including the definition of "interventional."

We received comments addressing the definition. Several commenters requested that the definition of "interventional" include a study (other than an observational study) of any approved or unapproved drug, biologic, device, radionuclide, or any other substance that is introduced into the human body during the study's experimental phase (*i.e.,* phase 0 through phase 4). As described in the preamble discussion for the definition of "applicable drug clinical trial," phase 0 and 1 studies are not included in the applicable clinical trials that must be registered under § 11.22, but such studies may still meet the definition of "interventional." The definition of "interventional" in the NPRM is generally consistent with what the commenters recommended, except that we provided more detail to help responsible parties apply the definition, including that interventional studies are those that: (1) Prospectively assign participants to an intervention, (2) do so according to a protocol, and (3) evaluate the intervention's effect on biomedical or other health-related outcomes. The commenters also described various types of observational studies that they believed would be excluded from this definition, including studies evaluating patients' responses independent of the actual ongoing clinical trial or other activities that have no direct interaction with the human body, but little detail was provided about these examples. However, we note that certain studies described by commenters did seem to fit the definition of "observational" (but not "interventional") because assignment to the intervention was based on routine care instead of a protocol, such as a study of patients receiving an intervention as part of routine medical care to assess any correlation between certain biomarkers and the intervention's effect.

Similarly, a commenter requested that the final rule clarify aspects of the "prospectively assigned to the intervention per protocol" component of the definition. The commenter asked specifically whether an intervention would be considered "prospectively assigned" if the administration of the test article began before subjects participated in the study (*i.e.,* the study assessed the effect of a therapy that was ongoing at the time of subject recruitment) and whether a drug provided as part of routine medical care would meet the requirement of being "prospectively assigned" if provision of the drug it occurred after subjects become research participants. In general, the timing of the intervention's administration in these cases would not be considered as relevant as how decisions for the participant to receive the intervention were made. If the decision for the participant to receive the intervention was based on routine medical care and not on assignment according to a protocol or research plan, the study would generally not be considered interventional. We note that there may be other aspects of the study design that were not described by the commenter that would otherwise cause the study to meet the definition of "interventional" (*e.g.,* other interventions are simultaneously being evaluated for their effect on outcomes related to human health, such as an IVD test). We also clarified in the NPRM that a study would meet the definition of "interventional" if assignment to the intervention is determined by the researcher based on a formal protocol or research plan, even when the medical products being studied are being used in a manner considered to be the standard of care (79 FR 69605). We also note, as discussed in Section V, that we will issue more guidance in the future on examples of applicable clinical trials for the checklist described in § 11.22.

Another comment requested clarification of the meaning of "biomedical or other health-related outcomes." We believe our explanation of "a prospective clinical study of health outcomes" for the definition of "applicable device clinical trial" is informative. In the NPRM, we explained that a "prospective clinical study of health outcomes" is a "clinical study in which the primary objective is to evaluate a defined clinical outcome related to human health" (79 FR 69599). For example, a clinical study of a diagnostic device (such as an IVD) in which the primary purpose is to evaluate the ability of the device to make a diagnosis of a disease or condition is related directly to human health and, therefore, would be considered a clinical study of health outcomes for purposes of this rule.

After considering these comments, we maintain the definition of "interventional" in the final rule to mean "with respect to a clinical study or a clinical investigation, that participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health-related outcomes." For the purposes of this part, we use the term "clinical trial" to refer to interventional studies to the exclusion of observational studies. (See the definition of "clinical trial.") The term "interventional" is one of the responses that can be submitted as part of the Study Type data element that is included as clinical trial registration information under § 11.28 and defined in § 11.10. Responsible parties must indicate whether a study being registered is "interventional" or "observational" or is expanded access (see the discussion below). A study that is designated as "interventional" can be an applicable clinical trial if it meets the other criteria for an applicable clinical trial that are specified in this part. (See the definitions of "applicable device clinical trial" and "applicable drug clinical trial.") A study that is designated "observational" can be an applicable clinical trial only if it is a pediatric postmarket surveillance of a device product as defined in this part. (See the definition of "pediatric postmarket surveillance of a device product.")

Investigational Device Exemption (IDE)

In the NPRM, we defined "Investigational Device Exemption (IDE)" in § 11.10(a) to have "the meaning given in 21 CFR 812, or any successor regulation'' (see 79 FR 69668). We did not receive any comments on this definition, and we maintain it in the final rule.

Investigational New Drug Application (IND)

In the NPRM, we defined ''Investigational New Drug Application (IND)'' in § 11.10(a) to have ''the meaning given in 21 CFR 312.3, or any successor regulation'' (see 79 FR 69668). We did not receive any comments on this definition, and we maintain it in the final rule.

NCT Number

In the NPRM, we defined ''NCT number'' in § 11.10(a) to mean ''the unique identification code assigned to each record in *ClinicalTrials.gov*, including a record for an applicable clinical trial, a clinical trial, or an expanded access program'' (79 FR 69606). ''NCT number'' refers to the term ''National Clinical Trial number'' used in section 402(j)(2)(B)(i)(VIII) of the PHS Act. We did not receive any comments on this definition, and we maintain it in the final rule.

Since its launch in 2000, *ClinicalTrials.gov* has assigned each submitted clinical trial record a unique identifier once quality review procedures have been completed for the submitted information. While the identifier was originally called a ''National Clinical Trial number,'' that nomenclature was soon changed to ''NCT number'' in recognition of the fact that *ClinicalTrials.gov* receives clinical trial information about trials being conducted in countries other than the United States and accommodates the registration of clinical studies other than clinical trials (*e.g.,* observational studies). NCT numbers are used in many contexts to refer to clinical trial records or other types of records (*e.g.,* observational studies, expanded access programs) that are accepted by *ClinicalTrials.gov*. Under the ICMJE registration policy, for example, journals publishing original papers on the results of clinical trials require the authors to include in their manuscripts a unique identification number assigned by a recognized clinical trial registry as evidence that the trial has been registered in compliance with the ICMJE policy [Ref. 1, 2]. For trials registered on *ClinicalTrials.gov,* this unique identifier is the NCT number. When published in journal articles, NCT numbers are also included in the Medical Literature Analysis and Retrieval System Online records and are searchable through PubMed [Ref. 87]. Furthermore, section 402(j)(5)(B) of the PHS Act specifies that ''such certification [to accompany drug, biological product, and device applications or submissions to FDA] shall include the appropriate National Clinical Trial control numbers.''

Ongoing

In the NPRM, we defined ''ongoing'' in § 11.10(a) to mean ''with respect to a clinical trial of a drug or a device and to a date, that one or more human subjects is enrolled in the clinical trial, and the date is before the completion date of the clinical trial.'' As we explained in the NPRM, this proposed definition is the same as the statutory definition, except the term ''human subjects'' has been substituted for the term ''patients'' that is used in section 402(j)(1)(A)(viii) of the PHS Act (79 FR 69606). The reason for this change is that clinical trials may include healthy volunteers as well as human subjects who might be considered ''patients.'' With respect to a pediatric postmarket surveillance of a device product, we defined the term ''ongoing'' to mean ''a date between the date on which FDA approves the plan for conducting the surveillance and the date on which the final report is submitted to FDA.''

We received comments addressing this definition. Two commenters asked that we clarify the definition and asserted that researchers consider trials to be ongoing even after the statutorily defined completion date. We note, though, that a trial cannot be considered ongoing in accordance with the statutory definition if the date is on or after the primary completion date (see the explanation above with regard to use of the term ''primary completion date''). Therefore, on or after the primary completion date, trials would not be considered ongoing for the purposes of this part and the applicable requirements.

After considering these comments, we maintain the NPRM definition of ''ongoing,'' except that (as discussed previously) we replace ''completion date'' with ''primary completion date,'' consistent with the definition of ''completion date'' in this section, and we clarify that ''drug'' means ''drug product'' and ''device'' means ''device product.'' We define ''ongoing'' in the final rule to mean ''with respect to a clinical trial of a drug product or a device product and to a date, that one or more human subjects is enrolled in the clinical trial, and the date is before the primary completion date of the clinical trial. With respect to a pediatric postmarket surveillance of a device product, ongoing means a date between the date on which FDA approves the plan for conducting the surveillance and the date on which the final report is submitted to FDA.''

Outcome Measure

In the NPRM, we defined ''outcome measure'' in § 11.10(a) to mean ''a pre-specified measurement that will be used to determine the effect of experimental variables on the human subjects in a clinical trial.'' As we explained in the NPRM, the experimental variables may be the specific intervention(s) used in the clinical trial or other elements of the clinical trial that vary between arms, *e.g.,* diagnostic or other procedures provided to participants in different arms (79 FR 69606). One commenter supported this definition.

We maintain the definition of ''outcome measure'' in the final rule except we make conforming changes to two elements, *i.e.,* we say ''an experimental variable'' and ''on the human subject(s)'' to be consistent with other definitions in the rule. In this part, ''outcome measure'' refers to measurements observed or collected from those human subjects who are enrolled in the clinical trial. Although it is not uncommon to compare data derived from human subjects enrolled in a clinical trial with data derived from other sources (*e.g.,* literature, other clinical trials), we believe that only measurements taken from participants in the clinical trial of interest should be submitted as results information to *ClinicalTrials.gov*. In our view, comparisons of such data with results data derived from other sources are more appropriately described in forums other than *ClinicalTrials.gov* (*e.g.,* journal articles) where the other necessary information about the comparator group can be provided. Clinical trial information submitted to *ClinicalTrials.gov* would generally not include information or data about the human subjects studied in another clinical trial (*i.e.,* the clinical trial record would not contain baseline and demographic information about them, nor would it describe how they were allocated to arms of the clinical trial to receive interventions). (See the definitions of ''primary outcome measure'' and ''secondary outcome measure.'')

Pediatric Postmarket Surveillance of a Device Product

Section 402(j)(1)(A)(ii)(II) of the PHS Act defines the term ''applicable device clinical trial'' to include ''a pediatric postmarket surveillance as required under section 522 of the [FD&C] Act.'' The term ''[a]pplicable device clinical trial'' includes ''a pediatric postmarket surveillance as required under[section

522 of the FD&C Act]." In the NPRM, we defined the term "pediatric postmarket surveillance of a device" in § 11.10(a) to mean "the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information conducted under section 522 of the [FD&C] Act about a marketed device that is expected to have significant use in patients who are 21 years of age or younger at the time of diagnosis or treatment (see 79 FR 69606). A pediatric postmarket surveillance of a device may be, but is not always, a clinical trial." Pursuant to section 522 of the FD&C Act, FDA defines the term "postmarket surveillance" as "the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device" (see 21 CFR 822.3(h)). In Title III of FDAAA, Congress directed that the term "pediatric," when used with respect to devices, refers to patients 21 and younger (see Title III of FDAAA ("Pediatric Medical Device Safety and Improvement Act of 2007"), amending section 520(m) of the FD&C Act).

FDA may order a pediatric postmarket surveillance of a device under section 522 of the FD&C Act for any class II or class III device, as defined by 21 U.S.C. 360c(a) and 21 CFR 860.3, meeting any of the following criteria: (1) Its failure would be reasonably likely to have serious adverse health consequences, (2) it is expected to have significant use in pediatric populations, (3) it is intended to be implanted in the body for more than 1 year, or (4) it is intended to be a life-sustaining or life-supporting device outside a device user facility (see 21 U.S.C. 360l(a)). Pediatric postmarket surveillances under section 522 of the FD&C Act can take various forms, including a detailed review of the complaint history and the scientific literature, non-clinical testing, observational studies, and controlled clinical trials.

Because section 402(j)(1)(A)(ii)(II) of the PHS Act defines the term "applicable device clinical trial" to include pediatric postmarket surveillances of a device, such surveillances must be registered, and clinical trial results information must be submitted for them. The final rule's approach for applying the registration requirements to a pediatric postmarket surveillance of a device that is not a clinical trial is described in § 11.28(b), and the final rule's approach for applying the results information submission requirements to a pediatric postmarket surveillance of a device that is not a clinical trial is described in § 11.48(b). A pediatric postmarket surveillance of a device that is a clinical trial is subject to the general requirements of this final rule, including the clinical trial registration and results information submission requirements in §§ 11.28(a) and 11.48(a), respectively.

We received no comments on this proposed definition, and we maintain it in the final rule. However, for clarity and consistency, "device" is changed to "device product." For completeness, we also include the applicable U.S.C. statutory citation in the definition.

Primary Completion Date

As discussed above, based on comments we received, we have decided to maintain the proposed rule's definition of "completion date" in § 11.10(a) of the final rule but, in order to prevent confusion among researchers and the public, we use the term "primary completion date" in this preamble and the codified provisions. Therefore, we add the term "primary completion date" to § 11.10(a), define it as "completion date," and refer to the definition of that term.

Primary Outcome Measure(s)

In the NPRM, we defined "primary outcome measure(s)" in § 11.10(a) to mean "the outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation. Most clinical trials have one primary outcome measure, but a clinical trial may have more than one." The NPRM also noted that, for the purpose of this part, "primary outcome" has the same meaning as "primary outcome measure" (79 FR 69606). The term "primary outcome measure(s)" is used, but not defined, in section 402(j) of the PHS Act. Section 402(j)(2)(A)(ii)(I)(ll) of the PHS Act expressly requires primary outcome measures to be submitted as a clinical trial registration information data element. In addition, section 402(j)(1)(A)(v) of the PHS Act defines the completion date in relation to the "final collection of data for the primary outcome." Primary outcome measure(s) is also expressly required as a clinical trial results information data element by section 402(j)(3)(C)(ii) of the PHS Act. As we explained in the NPRM, we believe this approach enables users of *ClinicalTrials.gov* to identify the pre-specified primary outcome measure(s) for the clinical trial submitted as part of the clinical trial registration information and to examine the results data collected for those outcome measures and submitted to the data bank as part of clinical trial results information. (See also the discussion in Sections IV.B.4 and IV.C.4 of this preamble regarding primary outcome measure as a clinical trial registration information data element in § 11.28(a)(2)(i)(W) and as a clinical trial results information data element in § 11.48(a)(3).) We received one comment in support of the proposed definition. We maintain the definition in the final rule, except, for greater clarity about the definition's scope, we add the phrase "for purposes of this part."

Principal Investigator

In the NPRM, we defined "principal investigator" in § 11.10 to mean "the individual who is responsible for the scientific and technical direction of the study." As we explained, "principal investigator" is a term used in the definition of "responsible party" in section 402(j)(1)(A)(ix) of the PHS Act and in the description of the Certain Agreements results data element in section 402(j)(3)(C)(iv) of the PHS Act, but the term itself is not defined in section 402(j) of the PHS Act (79 FR 69607). The definition uses terminology derived from 42 CFR 52.2, which defines "principal investigator" in the context of an NIH grant as "the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant and who is or are responsible for the scientific and technical direction of the project." We did not include the phrases "applicant organization" and "project or program supported by the grant," which are specific to NIH-funded grants, because these references would not necessarily apply to applicable clinical trials that are funded by industry or other non-governmental organizations. We used the term "study" in place of "project" because the projects of relevance to this rule would be clinical studies, whether clinical trials or pediatric postmarket surveillances of a device. We also made it clear that the definition applies to only a single individual. This is consistent with our interpretation that there cannot be more than one responsible party for a clinical trial that is subject to section 402(j) of the PHS Act. We would expect a principal investigator to have full responsibility for the treatment and evaluation of human subjects in the study and for the integrity of the research data for the full study. In keeping with this approach, an investigator for an individual site in a multi-site clinical trial would not be considered the principal investigator unless he or she also has overall responsibility for the clinical trial at all sites at which it is being conducted.

This interpretation is consistent with the requirement in section 402(j)(1)(A)(ix) of the PHS Act that a principal investigator may be designated by the sponsor as a responsible party only if he or she is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the clinical trial results, and has the ability to meet all the requirements for the submission of clinical trial information under section 402(j) of the PHS Act and this part.

We received comments on this proposed definition. Commenters requested that we make the proposed definition of "principal investigator" consistent with relevant FDA definitions. "Principal investigator" is not defined in FDA regulations or HHS "Common Rule" regulations (45 CFR part 46). However, FDA regulations in 21 CFR part 312 define "investigator" as "an individual who actually conducts a clinical investigation (*i.e.,* under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team" (see 21 CFR 312.3(b)). Other FDA regulations in 21 CFR parts 50, 56, and 812 define "investigator" similarly. The commenters noted that for large academic consortium studies, there may be an investigator who is responsible for the study's scientific and technical direction and who is commonly referred to as the "overall principal investigator" or "study director." As the commenters noted, FDA regulations do not define "principal investigator," and our proposed definition is for the purposes of this rule.

We do not believe that the proposed definition is inconsistent with FDA's definition of an "investigator." As we explained above, the definition is based on the NIH regulation applying to grants (42 CFR 52.2), with which academic medical centers should be familiar. We clarify that in the commenters' examples, the "overall principal investigator" or "study director" responsible for the study's overall scientific and technical direction would be considered the "principal investigator" for the purpose of this part. If there are clinical trials for which there is more than one individual whom the sponsor considers to be a principal investigator for the overall study, the sponsor may designate only one of these principal investigators as the responsible party. Another commenter also stated that the definition should include a qualifier to designate the principal investigator for the overall study (with multiple sites) or an individual site.

After considering these comments, we modify the definition of "principal investigator" to clarify that the principal investigator is responsible for the overall study (as distinguished from the individual study sites). The definition of "principal investigator" in the final rule means "the individual who is responsible for the overall scientific and technical direction of the study." We note that the principal investigator of a grant awarded by a Federal Government agency that funds a clinical trial may not necessarily be the principal investigator for that clinical trial for the purposes of this part. For example, for the purposes of grant funding, NIH defines "program director/principal investigator" in part as "[t]he individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award." [Ref. 87a]. Such an individual may or may not be "the individual who is responsible for the overall scientific and technical direction of the study" as defined in § 11.10(a) of this regulation.

In addition, the principal investigator on a Federal grant who has responsibility for only one site of a multi-site clinical trial (see, for example, 42 CFR 52.2) would neither have the requisite responsibility for conducting the entire trial nor the requisite access to data from all sites involved in the clinical trial, both of which are required by section 402(j) of the PHS Act and this part in order to meet the definition of "responsible party." Accordingly, the principal investigator on such a grant could not be designated by the sponsor to be the responsible party for the purposes of registering a clinical trial and submitting clinical trial results information under section 402(j) of the PHS Act and this part.

Protocol

In the NPRM, we defined "protocol" in § 11.10(a) to mean "the written description of the clinical trial, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations." As we explained in the NPRM, the protocol is the document that describes the design of a clinical trial. It may be, and frequently is, amended after a clinical trial has begun (79 FR 69607). This definition is derived from ICH E6(R1): Good Clinical Practice: Consolidated Guideline [Ref. 81] which defines the term as "[a] document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents." The protocol generally addresses major statistical considerations, such as the number of human subjects required to provide adequate statistical power, but it may or may not include detailed information about the specific statistical analyses to be performed as part of the clinical trial. Such information may be contained in a separate SAP. We received no comments on this definition, and we maintain it in the final rule. We note, for the purposes of this part, that the written description may vary in the degree of detail, structure, or format. This clarification is relevant for other definitions in this part that include the "protocol" component, including the definitions for "clinical trial" and "interventional."

Responsible Party

In the NPRM, we defined "responsible party" in § 11.10(a) to mean "with respect to a clinical trial, (i) the sponsor of the clinical trial, as defined in 21 CFR 50.3 (or any successor regulation); or (ii) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this part for the submission of clinical trial information. For a pediatric postmarket surveillance of a device that is not a clinical trial, the responsible party is the entity whom FDA orders to conduct the pediatric postmarket surveillance of a device." As we explained, "responsible party" is the term defined in section 402(j)(1)(A)(ix) of the PHS Act and used in section 402(j) of the PHS Act to refer to the entity or individual who is responsible for registering a clinical trial or a pediatric postmarket surveillance of a device that is not a clinical trial, for submitting clinical trial results information to *ClinicalTrials.gov,* and for updating all submitted clinical trial information (79 FR 69607). We received no comments on this definition, and we maintain it in the final rule. We have, however, made a minor formatting change and grammatical correction (changing "whom" to "who"). As we have elsewhere, we also now use the term "device product." The procedures for determining which individual or entity meets the definition of "responsible party" are specified in § 11.4(c) and described in Section IV.A.2 of this preamble. We address the comments on these procedures in that section.

Secondary Outcome Measure(s)

In the NPRM, we defined "secondary outcome measure" in § 11.10(a) to mean "an outcome measure that is of lesser importance than a primary outcome measure, but is part of a pre-specified plan for evaluating the effects of the intervention or interventions under investigation in a clinical trial." As we explained in the NPRM, a "clinical trial may have more than one secondary outcome measure" (79 FR 69607). We also noted that for the purpose of this part, "secondary outcome" has the same meaning as "secondary outcome measure." "Secondary outcome measure" is a term used, but not defined, in section 402(j) of the PHS Act. Section 402(j)(2)(A)(ii)(I)(ll) of the PHS Act expressly requires secondary outcome measures to be submitted as a clinical trial registration information data element, as a component of the outcome measures data element. In addition, secondary outcome measure(s) is also expressly required as a clinical trial results information data element by section 402(j)(3)(C)(ii) of the PHS Act. As we said, we believe this structure enables users of *ClinicalTrials.gov* to identify the pre-specified secondary outcome measures for the clinical trial submitted as part of the clinical trial registration information and to examine the results data collected for those outcome measures and submitted to the data bank as part of clinical trial results information. We also pointed out that the definition is consistent with the WHO Trial Registration standard and ICMJE registration policies [Ref. 2, 73].

We received comments on this definition. One commenter supported this definition. We also heard from others that we should clarify whether any outcomes that are not part of the SAP, or are indicated to be tertiary or exploratory, are secondary outcome measures. We consider secondary outcome measures to be those outcome measures (other than the primary outcome measures) that are not considered exploratory or tertiary and for which there is a specific analysis plan. In general, the analysis plan would be specified in the protocol or SAP, but protocols do not always contain detailed information about statistical analyses, and SAPs may not be complete at the time a trial is registered. Therefore, the plan to analyze the secondary outcome measures may only be expressed in other formal trial documentation (*e.g.,* a grant application, contract, or published journal article). Therefore, in response to these comments, we confirm that outcome measures that are not part of an analysis plan, or are indicated to be exploratory or tertiary, are lower-level outcome measures and not secondary outcome measures. These lower-level outcome measures are not required to be submitted to *ClinicalTrials.gov*, but the information may be submitted voluntarily. (See the discussions in Sections IV.B.4 and IV.C.3 of this preamble, respectively, regarding secondary outcome measure(s) as a clinical trial information data element to be submitted at the time of registration, pursuant to § 11.28(a)(2)(i)(X), and at the time of results information submission, pursuant to § 11.48(a)(3).) After consideration of these comments, we clarify that a pre-specified exploratory or tertiary measure is not considered a secondary outcome. The definition of "secondary outcome measure(s)" in § 11.10(a) of this final rule is "an outcome measure that is of lesser importance than a primary outcome measure, but is part of a pre-specified analysis plan for evaluating the effects of the intervention or interventions under investigation in a clinical trial and is not specified as an exploratory or other measure. A clinical trial may have more than one secondary outcome measure." For the purpose of this part, "secondary outcome" has the same meaning as "secondary outcome measure." We include the phrase "and is not specified as an exploratory or other measure" to be clear that a pre-specified exploratory or other measure is not considered a secondary outcome measure.

Secretary

In the NPRM, we defined "Secretary" in § 11.10(a) to mean "the Secretary of Health and Human Services or any other official(s) to whom the Secretary delegates authority contained in 42 U.S.C. 282(j)" (see 79 FR 69669). We received no comments on this definition. We maintain it, except that we make clear that that the Secretary's authority is contained in "section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)."

Serious Adverse Event

In the NPRM, we defined "serious adverse event" in § 11.10(a) to mean "an adverse event that results in any of the following outcomes: Death, a life-threatening adverse event as defined in 21 CFR 312.32 (or any successor regulation), inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the human subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of a substance use disorder." As we explained in the NPRM, "serious adverse event" is a term used, but not defined, in section 402(j)(3)(I) of the PHS Act (79 FR 69608). Section 402(j)(3)(I)(iii)(I) of the PHS Act requires the submission to *ClinicalTrials.gov* of specific information about "anticipated and unanticipated serious adverse events" for applicable clinical trials of drugs as well as devices.

We received comments on this definition. Commenters suggested that the adverse event reporting requirements for devices should be consistent with the definition of "serious adverse event" used by the international standard for clinical investigations of medical devices in human subjects (ISO 14155) [Ref. 88]. As we noted in our discussion of the term in the NPRM, the definition is consistent with established FDA standards, and we drew on the FDA definition of "serious adverse event" in 21 CFR 312.32(a) for IND applications in developing the definition because that FDA definition more fully characterizes the criteria for "other serious problems" as well as "any life-threatening problem" or "[d]eath." In defining the term "serious adverse event" in its IND Safety Reporting regulations in 21 CFR 312.32(a), FDA considers an adverse event to be "serious" when, in the view of either the sponsor or the investigator, it "results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse." The other points we made in the NPRM are also relevant, and we reiterate them here to explain why we are not adopting the commenters' suggestion. A "serious adverse event," as defined in 21 CFR 312.32(a), applies only in the context of drugs (including biological products). No fully equivalent term is defined in FDA regulations for medical devices. In 21 CFR 812.3(s), FDA defines an "unanticipated adverse device effect" as, in part, "any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device" that "was not previously identified . . . in the investigational plan or application . . . or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects." However, we did not consider this definition to be sufficient to meet the statutory requirement in section 402(j)(3)(I)(iii) of the PHS Act for submission of serious adverse event information that encompasses both anticipated and unanticipated events because it is restricted to unanticipated effects.

After considering the comments, we maintain the NPRM definition of "serious adverse event" in § 11.10(a) to mean "an adverse event that results in any of the following outcomes: Death, a life-threatening adverse event as defined in 21 CFR 312.32, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the human subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of a substance use disorder." Although we adopted terms from an FDA drug regulation, we emphasize that "serious adverse event," as defined for the purposes of this part, applies to both drugs and devices. Further, and as explained more fully in section IV.C.4. of this preamble, the rule does not require investigators or responsible parties to collect information that is not specified in the clinical trial protocol.

We use the phrase "a substance use disorder" instead of the phrase "drug dependency or drug abuse," which is used in the FDA definition, for consistency with the latest version (fifth edition) of the Diagnostic and Statistical Manual of Mental Disorders [Ref. 89]. By referring to adverse events (and thus the definition of that term in this part), our definition of "serious adverse event" is broader than the FDA definition of "serious adverse event" in 21 CFR 312.32(a) because it encompasses any untoward or unfavorable medical occurrences associated with any intervention included in a clinical trial (not just the use of the FDA-regulated product), including any intervention(s) in any arm of the clinical trial that does not involve FDA-regulated products. In addition, as with our definition of "adverse event," our definition of "serious adverse event" encompasses both anticipated and unanticipated effects regardless of attribution or association with the intervention.

Sponsor

In the NPRM, we defined "sponsor" in § 11.10(a) to mean "either a 'sponsor' or 'sponsor-investigator,' as each is defined 21 CFR 50.3 or any successor regulation." As we explained, "[s]ponsor" is a term used in section 402(j) of the PHS Act to define responsible party (79 FR 69608). Section 402(j)(1)(A)(ix)(I) of the PHS Act explicitly defines "sponsor" as such term is defined at 21 CFR 50.3 or any successor regulation. Two types of sponsors are defined in 21 CFR 50.3, both of which, we noted, meet the definition of "sponsor" for the purposes of this part. The first type is a "sponsor," defined in 21 CFR 50.3 as "a person who initiates a clinical investigation but who does not actually conduct the investigation, *i.e.,* the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (*e.g.,* corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators." The second type is a "sponsor-investigator," defined in 21 CFR 50.3 as "an individual who both initiates and actually conducts, alone or with others, a clinical investigation, *i.e.,* under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, *e.g.,* corporation or agency." As we noted, we believe that the definition of "sponsor" used in this part must encompass both a sponsor and a sponsor-investigator because both terms are relevant in determining who initiates the clinical trial.

We did not receive any comments on this definition, and we maintain it in the final rule to mean "either a 'sponsor' or 'sponsor-investigator', as each is defined 21 CFR 50.3." Procedures for determining which individual or entity would be considered the sponsor of an applicable clinical trial or other clinical trial subject to this part are specified in § 11.4(c) and described in Section IV.A.2 of this preamble. As those sections explain, the individual or entity that is the sponsor is considered to be the responsible party of an applicable clinical trial or other clinical trial, unless and until that responsibility is delegated to the principal investigator, consistent with the requirements of section 402(j)(1)(A)(ix) of the PHS Act and this part.

Study Completion Date

The NPRM did not use the term "study completion date" or propose either a definition of it in § 11.10(a) or a data element for it in § 11.28, but we are including the term and data element in this final rule. We define the term "study completion date" in § 11.10(a) to mean "for a clinical trial, the date the final subject was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (*e.g.,* last subject's last visit), whether the clinical trial concluded according to the pre-specified protocol or was terminated." Section 402(j)(2)(A)(ii) of the PHS Act specifies the clinical trial registration information that must be submitted, although study completion date is not included. However, section 402(j)(2)(A)(iii) of the PHS Act permits the Secretary to "modify the requirements for clinical trial [registration] information" by regulation, provided that "such a modification improves and does not reduce such clinical trial information."

As discussed in Section IV.B.4, we believe that the study completion date is helpful in indicating when all primary and secondary outcome measures and the collection of all adverse event information, as specified in the protocol, will be completed and when final data collection has occurred. Therefore, we believe that requiring the submission of the study completion date improves and does not reduce clinical trial information.

Section 11.64(a)(3) describes when a responsible party's obligation to submit updates ends. Our definition of "study completion date" identifies the final date of data collection for the study, including for any primary and secondary outcomes and for adverse events. For adverse events, the last date of data collection is the end of the adverse event collection period specified by the protocol. The study completion date will be the end of this adverse event collection period if this period ends later than the last subject's last visit for the primary and secondary outcomes. As discussed in other sections of this preamble, the study completion date is relevant in determining the obligations for responsible parties to submit registration and results information. As described in Section IV.C.3 for partial results information deadlines under § 11.44(d), clinical trial results information specified in § 11.48 must be submitted no later than one year after the study completion date. In addition, the Study Completion Date," which is a registration data element, will be displayed on the posted record.

Although we did not receive any specific comments about adding a Study Completion Date data element, commenters did request that a mechanism be included in the PRS to make clear to responsible parties when they have fulfilled all obligations to update the study record, and when no further updates are required. A responsible party can use the "study completion date" definition and related data element in determining various obligations under this part, such as the deadlines for submitting partial results information under § 11.44(d). The "study completion date" is distinct from "completion date," which, as discussed above, we refer to as the "primary completion date."

U.S. FDA-Regulated Device Product

In the NPRM, we defined "FDA-regulated device" in § 11.10(a) to mean "for purposes of this part, a device subject to section 510(k), 515, 520(m), or 522 of the Federal Food, Drug, and Cosmetic Act." As we explained, this term and its definition are based on section 402(j)(1)(A)(ii) of the PHS Act, which defines "applicable device clinical trial" as including studies of a "device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act." We did not receive any comments on this definition and maintain it in § 11.10(a) of the final rule. However, because "FDA" is a term used by similar regulatory agencies in other countries, we have changed the term "FDA-regulated device" to "U.S. FDA-regulated device product" for clarity. As we have elsewhere, we now also use the term "device product." A responsible party must submit information, in accordance with § 11.28, about whether the trial "studies a U.S. FDA-regulated device product." We explain further whether a trial studies a U.S. FDA-regulated device product in Section IV.B.2 of this preamble in our elaboration on the meaning of an "applicable device clinical trial." We also include the applicable U.S.C. statutory citations in the definition.

U.S. FDA-Regulated Drug Product

In the NPRM, we defined "FDA-regulated drug" in § 11.10(a) to mean "for purposes of this part, a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or a biological product subject to section 351 of the Public Health Service Act." As we explained, this term and its definition are based on section 402(j)(1)(A)(iii) of the PHS Act, which defines "applicable drug clinical trial" as including studies of a "drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the [Public Health Service Act]." We did not receive any comments on this definition and maintain it in § 11.10(a) of the final rule. However, because "FDA" is a term used by similar regulatory agencies in other countries, we have changed the term "FDA-regulated drug" to "U.S. FDA-regulated drug product" for further clarity. Additionally, for clarity, we now use the term "drug product" rather than "drug." A responsible party must submit information in accordance with § 11.28 about whether the trial "studies a U.S. FDA-regulated drug product." We explain further whether a trial studies a U.S. FDA-regulated drug product in Section IV.B.2 of this preamble in our elaboration on the meaning of an "applicable drug clinical trial". We also include the applicable U.S.C. statutory citations in the definition.

Section 11.10(b) defines certain data elements that are part of the clinical trial registration information that must be submitted to *ClinicalTrials.gov* under this part. The data elements defined in § 11.10(b) are enumerated in § 11.28(a).

B. Subpart B—Registration

1. 11.20—Who must submit clinical trial registration information?

Overview of Proposal

Proposed § 11.20 required that "[t]he responsible party for an applicable clinical trial specified in § 11.22 must register the applicable clinical trial by submitting clinical trial registration information specified in § 11.28 for that clinical trial." As we explained in the NPRM, this approach is consistent with section 402(j)(2)(C) of the PHS Act, which states that the "responsible party for an applicable clinical trial . . . shall submit to the Director of NIH for inclusion in the registry data bank the [clinical trial registration information]" (79 FR 69609).

Comments and Response

There were no comments received on this section.

Final Rule

The final rule maintains § 11.20 as proposed, except clarifies the wording for consistency with § 11.40. Section 11.20 requires that "[t]he responsible party for an applicable clinical trial specified in § 11.22 must submit clinical trial registration information for that clinical trial."

2. 11.22—Which applicable clinical trials must be registered?

Overview of Proposal

In proposed § 11.22(a), the Agency interpreted section 402(j)(2)(C) of the PHS Act to specify which applicable clinical trials must be registered with *ClinicalTrials.gov.* As we explained in the NPRM, proposed § 11.22(b) set forth an approach for determining whether or not a clinical trial meets the statutory definitions of an applicable device clinical trial and an applicable drug clinical trial, as established in section 402(j)(1) of the PHS Act (79 FR 69610). The proposed approach used a series of specific registration data elements and corresponding criteria to determine whether a clinical trial or study meets the definition of an applicable clinical trial (*i.e.,* Study Type of the trial is "interventional," Study Phase is other than "Phase 1," etc.). We also pointed out that "algorithms" following the approach outlined in the regulations would also be made available outside the registration process (*e.g.,* online at *http://prsinfo.clinicaltrials.gov/fdaaa.html*), and study sponsors could use such algorithms to evaluate whether a particular trial meets the definition of applicable clinical trial (79 FR 69610). The NPRM invited public comment on the approach proposed in § 11.22(b) for determining whether a clinical trial or study is an applicable clinical trial. It also requested comments on whether there are any types of applicable clinical trials that would be misidentified by this approach.

Comments and Response

Commenters addressed the NPRM's approach for facilitating the determination of which clinical trials or studies are applicable clinical trials that must be registered with *ClinicalTrials.gov.* Several commenters supported the proposed approach for determining whether a study is an applicable clinical trial, with a few commenters suggesting that the rationale and approach would likely reduce administrative burden for stakeholders. One suggested that the data elements required for the determination process be made available to sponsors outside of the registration process and that *ClinicalTrials.gov* issue dated receipts to provide an audit trail detailing whether or not a clinical trial was determined to be an applicable clinical trial. In order to assist users in evaluating, prior to beginning the registration process, whether their clinical trial or study is an applicable clinical trial and potentially subject to the requirements of the statute and the final rule, a checklist-based tool will be made available at *https://prsinfo.clinicaltrials.gov* (or successor site) for sponsors and others before the effective date of the rule. Although proposed § 11.22(b) included the criteria for determining whether a trial is an applicable clinical trial, the checklist tool is external to the *ClinicalTrials.gov* PRS and separate from the registration process. The outcome generated by the checklist tool will not be retained by the Agency and will not be binding on either the user or any government Agency in any future actions. While the tool is intended to be useful, it is not intended to be determinative of the applicability of the statute or this rule. Thus, we do not agree that a dated receipt for the outcome is necessary.

A few commenters opposed the overall proposed approach. One stated that it would be neither helpful nor appropriate and requested that study sponsors be allowed to make the determination rather than respond to each specific element. As noted, the Agency is not making the checklist tool available within the internal PRS system. The proposed approach provides responsible parties or other users with a method to help evaluate whether a particular clinical trial is an applicable clinical trial prior to data submission. Since 2009, a draft Elaboration of Definitions, which expounds on the definition of applicable clinical trial [Ref. 90], and *ClinicalTrials.gov* registration data elements have been available to allow sponsors to indicate whether a clinical trial or study is an applicable clinical trial (*i.e.,* "Section 801 Clinical Trial") [Ref. 85]. However, based on requests for clarification we have received to date, some users have found application of these definitions and data elements difficult to implement in practice. Building on our experience in responding to such requests and the comments received, breaking the definition of applicable clinical trial into components that can be explained in terms of objective data elements has often facilitated understanding of the applicable clinical trial definition and the user's evaluation process for their particular clinical trial or study. Other than comments on the interpretation of the definition of applicable clinical trial and its components (*e.g.,* definition of "controlled," application to studies of "combination products"), which are discussed elsewhere in the preamble (see Section IV.A.5), we did not receive any specific examples, as invited, of situations in which the proposed approach would misidentify an applicable clinical trial. However, as addressed below, other commenters offered suggestions or raised questions about our proposal.

Some commenters observed that the data elements used for the Applicable Clinical Trial assessment checklist were either too broadly or too poorly defined. One commenter suggested that additional data elements be added to determine whether a study is interventional. We clarify or provide elaboration on the definitions (see § 11.10) for a number of data elements, such as "interventional," used to determine whether a study is an applicable clinical trial. In addition, we are committed to providing additional guidance as needed when new issues with interpretation are raised. The Agency believes that this data element-based approach provides an objective, transparent set of criteria for responsible parties and other users to evaluate, prior to registering a trial, whether a clinical trial or study is an applicable clinical trial and for such users of *ClinicalTrials.gov* to understand the data elements used in evaluating whether a clinical trial or study is an applicable clinical trial. Prior to registration a sponsor or other user will be able to use the external checklist tool, which will be based on the set of data elements identified in § 11.22(b), to assess whether a clinical trial or study is considered an applicable clinical trial. Once clinical trial registration information has been submitted, the Agency will be able to identify applicable clinical trials based on the set of data elements identified in § 11.22(b). Public users of *ClinicalTrials.gov*, other than responsible parties, should be able to understand whether a registered trial is an applicable clinical trial. Although we have not conducted a formal pilot study, as suggested by a commenter, the approach is responsive to the challenges users have experienced in the past while trying to determine whether their clinical trial or study meets the definition of applicable clinical trial.

Commenters requested that the Agency provide examples of clinical trials that do not fulfill the proposed criteria for applicable clinical trials, and a couple of commenters observed that case studies would be helpful for clarification purposes. The Agency intends to continue making explanatory documents and other materials available, including examples, case studies, and a publicly-accessible checklist-based tool (described above) consisting of the relevant data elements and detailed explanation of each criterion at *https://prsinfo.clinicaltrials.gov* (or successor stite). Finally, the Agency believes that it has identified the minimum set of criteria (corresponding to the registration data elements) needed to identify applicable clinical trials, which should minimize burden on the responsible parties.

Several commenters recommended that the Agency provide responsible parties with a mechanism to explain why a clinical trial is not an applicable clinical trial and/or to appeal the outcome of the proposed approach. However, although we specifically asked in the NPRM for examples of cases in which the approach outlined in the NPRM and discussed above would lead to a misclassification of a clinical trial (*i.e.,* either by inappropriately including a trial that is not an applicable clinical trial or excluding a trial that is), no examples were submitted. Further, as mentioned previously, the checklist will be available as a tool separate from the *ClinicalTrials.gov* registration process in the PRS. By having each criterion correspond to one or more standard data elements, the evaluation and assessment process follows a checklist approach based on factual information (*e.g.,* whether or not the Study Type is "interventional" as defined; whether a drug is regulated by the U.S. FDA under section 505 of the FD&C Act or section 351 of the PHS Act). Responsible parties or other users who use the checklist tool are responsible for using accurate data about a clinical trial or study and for conducting the evaluation. Since the outcome is dependent on the factual data relied on by a responsible party or other user, and the outcome of the assessment will not be binding on either the user or any government Agency in any future actions, we do not see a need for a mechanism for responsible parties or other users to comment on a particular outcome of the external checklist tool or an appeal process to dispute the outcome. The Agency will provide contact information for obtaining assistance with questions that arise about the interpretation of a criterion or a relevant data element definition for which answers cannot be found in Agency documents or other existing materials.

Another commenter requested that the *ClinicalTrials.gov* Web site remove the "late" status and "problems" designation for trials that do not meet the definition of "applicable clinical trial" under the regulation. It is our understanding that this comment refers to an online tool that is currently available to help responsible parties manage their study records when using the PRS. Since all of the data elements needed to evaluate whether a clinical trial or study is an applicable clinical trial are not yet available, the current online tool only approximates which submissions may be "late" and which trials are "*probable* applicable clinical trials." The Agency used the term "probable applicable clinical trials" (pACTs) to refer to the estimated number of clinical trials subject to section 402(j) of the PHS Act prior to the effective date of the rule. This approach relied on the set of clinical trial registration data elements available prior to enactment of the final rule, but did not include all of the data elements necessary to determine which studies are applicable clinical trials as specified in § 11.22(b) of the final rule. The pACTs were defined as records listing an "interventional" Study Type; with at least one Intervention Type as "Biological," "Drug," "Device," "Genetic," or "Radiation;" a Study Phase other than "Phase 0" or "Phase 1;" a Primary Completion Date on or after January 2008 or, if the Primary Completion Date was missing, a Study Completion Date on or after January 2008, or any record for which both the Primary Completion Date and the Study Completion Date are missing; an Overall Recruitment Status other than "Withdrawn," and at least one Facility Location Country in the "United States" or if none, indication that the study is conducted under an FDA IND or IDE.

Promulgation of the final rule and implementation of several new data elements (*e.g.,* Studies an FDA-regulated Drug [or Device]), enables the Agency to be better able to identify applicable clinical trials more accurately in the PRS and on the public Web site. In addition, it enables the Agency to create other tools within the PRS to assist responsible parties with managing their responsibilities. Misidentified trials, as referred to in the comments, should be able to be addressed.

Final Rule

Taking into consideration the submitted comments, as well as the statutory definitions of the terms, "applicable device clinical trial" and "applicable drug clinical trial," the rule retains the proposed scope for required registration of applicable clinical trials, but modifies the approach for evaluating whether a study is an applicable clinical trial as specified in § 11.22(b) based on the Agency's revised interpretation of "control or controlled," as described elsewhere in the preamble (Section IV.A.5). Additionally, the final rule clarifies that "device" means "device product" and "drug" means "drug product." The final rule also clarifies that the approach in § 11.22(b) for evaluating whether a study is an applicable clinical trial applies to trials initiated on or after the effective date of the final rule.

Section 11.22(a)(1) and (2) state that registration is required for: (1) "[a]ny applicable clinical trial that is initiated after September 27, 2007;" and (2) "[a]ny applicable clinical trial that is initiated on or before September 27, 2007 and is ongoing on December 26, 2007 [. . .]." Section 11.22(a)(3) provides clarification for determining the date on which an applicable clinical trial is initiated, stating that "[a]n applicable clinical trial, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, is considered to be initiated on the date on which the first human subject is enrolled."

Based on the Agency's interpretation of the term "applicable device clinical trial" as defined in section 402(j)(1) of the PHS Act, § 11.22(b)(1) states that a clinical trial is considered an applicable device clinical trial if (1) it is a pediatric postmarket surveillance of a device product required by FDA under section 522 of the FD&C Act (regardless of whether the pediatric postmarket surveillance is a clinical trial), or (2) it is a clinical trial with one or more arms that meets all of the following criteria: (a) The Study Type is interventional; (b) the Primary Purpose selected is any other than feasibility; (c) the clinical trial Studies a U.S. FDA-regulated Device; and, (d) one or more of the following applies: At least one Facility Location is within the U.S. or one of its territories, the device under investigation is a Product Manufactured in and Exported from the U.S. or one of its territories for study in another country, or the clinical trial has a U.S. Food and Drug Administration IDE Number. We also note that the final rule does not include the proposed criterion regarding the Number of Arms and Single Arm Controlled data elements in § 11.22(b)(1)(ii)(C) and (b)(2)(iii) of the NPRM because the Agency considers all clinical trials with one or more arms and pre-specified primary or secondary outcome measures controlled for purposes of the final rule (see discussion of "control or controlled" in Section IV.A.5 of this preamble).

Based on the Agency's interpretation of the term "applicable drug clinical trial" as defined in section 402(j)(1) of the PHS Act, § 11.22(b)(2) states that a clinical trial with one or more arms is considered an applicable drug clinical trial if it meets all of the following: (1) The Study Type is interventional; (2) the Study Phase is other than phase 1; (3) the clinical trial Studies a U.S. FDA-regulated Drug Product; and, (4) one or more of the following applies: At least one Facility Location is within the U.S. or one of its territories, the drug product under investigation is a Product Manufactured in and Exported from the U.S. for study in another country, or the clinical trial has a U.S. Food and Drug Administration IND Number.

With respect to Study Phase and the determination process, we do not consider a phase 1/phase 2 trial (*i.e.,* a trial with characteristics of both phase 1 and phase 2 studies trials) to be a phase 1 trial. If a clinical trial is initially registered as phase 1/phase 2 trial, it is considered to be a phase 2 trial. If the trial subsequently proceeds through only the phase 1 stage and/or is terminated before reaching phase 2, the Study Phase data element may be updated to indicate that the trial is a phase 1 trial, in which case it would not be considered an applicable drug clinical trial and would not be subject to the requirements for results information submission specified in subpart C. However, submitted registration information would continue to be posted in the *ClinicalTrials.gov* data bank.

While most applicable clinical trials will meet the definition of either an applicable device clinical trial or an applicable drug clinical trial, some applicable clinical trials that study multiple intervention types (*e.g.,* in different arms of the clinical trial) could meet both definitions. For example, a clinical trial with facility locations in the U.S. that studies a U.S. FDA-regulated drug product in one arm, studies a U.S FDA-regulated device product in another arm, and compares outcomes of the two arms would meet both definitions. If the U.S. FDA-regulated device product studied in such an applicable clinical trial is not approved or cleared by FDA for any use, we will not post clinical trial registration information for that applicable clinical trial prior to the date of approval or clearance of the device product, consistent with § 11.35(b)(2)(i), unless the responsible party indicates, pursuant to § 11.35(b)(2)(ii), that it authorizes such posting.

3. 11.24—When must clinical trial registration information be submitted?

Overview of Proposal

Proposed § 11.24 specified the deadlines by which a responsible party must submit clinical trial registration information for an applicable clinical trial to *ClinicalTrials.gov*, implementing section 402(j)(2)(c) of the PHS Act. As explained in the NPRM, proposed § 11.24(a) specified the general registration deadline requiring submission by the later of December 26, 2007, or 21 calendar days after enrollment of the first human subject in a clinical trial, as specified in section 402(j)(2)(C)(i) and (ii) (79 FR 69611). Proposed § 11.24(b) implemented two exceptions: (1) For applicable clinical trials that are not for a serious or life-threatening disease or condition and that were initiated on or before enactment of FDAAA, the registration deadline is not later than September 27, 2008, or 21 calendar days after the first human subject is enrolled, whichever date is later, consistent with section 402(j)(2)(C)(iii) of the PHS Act, and (2) for a pediatric postmarket surveillance of a device product that is not a clinical trial, which is defined as an applicable device clinical trial in section 402(j)(1)(A)(ii)(II) of the PHS Act, the registration deadline is not later than December 26, 2007, or 21 calendar days after FDA approves the postmarket surveillance plan, whichever date is later (79 FR 69611).

Comments and Response

Commenters addressed the registration submission deadlines in proposed § 11.24. The commenters suggested that the final rule require general registration prior to enrollment of the first human subject, rather than allow up to an additional 21 calendar days as proposed. One commenter noted that such a deadline would be consistent with requirements specified in the EU Clinical Trials Regulation as well as the Declaration of Helsinki. Another commenter also requested that the final rule omit the exception to the general deadline for registering applicable clinical trials not for a serious or life-threatening disease or condition specified in proposed § 11.24(b)(1). The Agency is not revising proposed § 11.24 as suggestedby the comments. Section 11.24 accurately reflects the statutory requirements for submission of registration information.

Final Rule

Taking into consideration the commenters' suggestions and the statutory requirements for registration information submission deadlines, the final rule maintains the approach proposed in § 11.24(a) and (b) except that it clarifies that "device" means "device product." In addition, we have clarify that the clinical trial registration information that must be submitted will either be the information specified in section 402(j)(2)(A)(ii) of the PHS Act or in § 11.28(a). Consistent with the discussion in section IV.F., the requirements for applicable clinical trials will differ based on the initiation date of the applicable clinical trial. Final § 11.24(a) generally requires a responsible party to submit clinical trial registration information 21 calendar days after the first human subject is enrolled in the clinical trial. Final § 11.24 also provides exceptions to this general registration submission deadline for applicable clinical trials that are clinical trials and were (1) initiated on or before September 27, 2007, and (2) ongoing as of December 26, 2007. For applicable clinical trials for a serious or life-threatening disease or condition, responsible parties were required to submit registration information by December 26, 2007, under § 11.24(a). Examples of serious or life-threatening diseases or conditions include acquired immunodeficiency syndrome, all other stages of human immunodeficiency virus (HIV), Alzheimer's disease, cancer, or heart failure [Ref. 78, 79]. For applicable clinical trials not for a serious or life-threatening disease or condition, responsible parties were required to submit registration information by September 27, 2008, under § 11.24(b)(1).

4. § 11.28—What constitutes clinical trial registration information?

§ 11.28—Overall

Overview of Proposal

Proposed § 11.28 identified the structured information, or data elements, that constitute clinical trial information that a responsible party must submit in order to register an applicable clinical trial. Section 402(j)(2)(A)(ii) of the PHS Act specifies a number of data elements that must be submitted to *ClinicalTrials.gov* for registration. In general, the proposed data elements in § 11.28 conformed to the items enumerated in section 402(j)(2)(A)(ii) of the PHS Act. In many instances, the Agency, through the proposed rulemaking, had restated or clarified the registration data elements required by section 402(j)(2)(A)(ii) of the PHS Act. In addition, section 402(j)(2)(A)(iii) of the PHS Act expressly authorizes the Secretary to modify the registration data elements, by regulation, if a rationale is provided as to why such a modification "improves and does not reduce" such information. In developing the proposed set of data elements for registration, we carefully considered the items enumerated in section 402(j)(2)(A)(ii) of the PHS Act, the mandate in section 402(j)(2)(A)(i) to "expand" the existing registration data bank, and the intent to expand the data bank "to enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials" (see section 402(j)(2)(A)(i) of the PHS Act). We also took into consideration the WHO Trial Registration Data Set and have sought to maintain consistency with the clinical trial registration requirements of ICMJE [Ref. 73, 2].

As we noted in the NPRM, careful consideration was given to the data elements that were part of the data bank prior to passage in 2007 of section 402(j) of the PHS Act, some of which are not expressly required under section 402(j)(2)(A)(ii) of the PHS Act, but which we considered necessary to fulfill both the purpose of the expansion of registration information contained in *ClinicalTrials.gov* and certain other requirements of section 402(j) of the PHS Act. We later consulted with a wide range of groups, including the NLM Board of Directors Working Group on Clinical Trials, internal NIH and joint NIH–FDA working groups and committees, the FDA Risk Communication Advisory Committee, the HHS Secretary's Advisory

Committee on Human Research Protections, the Drug Information Association Clinical Trial Disclosure Special Interest Area Community, and a Clinical and Translational Science Awards *ClinicalTrials.gov* Task Force [Ref. 72, 91, 91]. We believe, in general, that maintaining consistency with the pre-existing *ClinicalTrials.gov* data elements is consistent with the intent of section 402(j) of the PHS Act. Not only do we presume that Congress was familiar with those existing definitions when it developed and passed section 402(j) of the PHS Act, we also believe that maintaining consistency achieves several important goals. It is intended to minimize confusion for those who submitted registration information to *ClinicalTrials.gov* prior to enactment of section 402(j) of the PHS Act as well as minimize the level of effort required by those who previously established automated computer-based processes for submitting and updating registration data in *ClinicalTrials.gov*, rather than entering the data manually into the data bank. We believe that maintaining consistency serves the public by facilitating cross-comparison of entries made before and after enactment of section 402(j) of the PHS Act and that it also ensures that the proposed clinical trial registration information requirements would not have the effect of reducing the amount of information available for newly registered clinical trials as compared to those registered prior to the passage in 2007 of section 402(j) of the PHS Act, a result that we believe would be contrary to the intent of section 402(j) of the PHS Act. For these reasons, we believe that requiring the submission of data elements that were expected to be submitted to *ClinicalTrials.gov* prior to the passage in 2007 of section 402(j) of the PHS Act in order to register a clinical trial improves and does not reduce the clinical trial information submitted to *ClinicalTrials.gov*.

While developing our proposed set of data elements for clinical trial registration information for the NPRM, we decided to exercise our authority under section 402(j)(2)(A)(iii) of the PHS Act to modify the section 402(j)(2)(A)(ii) requirements for registration information in order to achieve the following objectives:

(1) Specify a particular structure for submitting certain clinical trial registration information in order to (a) help the public use the data bank more easily and be able to compare entries, consistent with section 402(j)(2)(B)(iv) of the PHS Act; (b) enable searching of the data bank using criteria listed in sections 402(j)(2)(B)(i) and (ii) of the PHS Act; and (c) facilitate the submission of complete and accurate information by responsible parties.

(2) Enable effective implementation of, or compliance with, other provisions of section 402(j) of the PHS Act and this part, *e.g.,* proposed adding data elements to indicate whether a product under study in a clinical trial is manufactured in the United States and whether a study is a pediatric postmarket surveillance of a device product, both of which are important to help determine whether a study meets the definition of an applicable clinical trial.

(3) Improve the quality and consistency of clinical trial registration information, *e.g.,* proposed adding the Other Intervention Name(s) and Intervention Description data elements to help users identify and differentiate among similar interventions studied in registered clinical trials.

(4) Demonstrate whether clinical trials registered in the data bank have complied with ethical and scientific review procedures in accordance with applicable statutes and regulations, *e.g.,* proposed adding the Human Subjects Protection Review Board Status data element to indicate to potential human subjects and other users whether an applicable clinical trial has received needed approvals or is not subject to such requirements (79 FR 69611).

Several commenters supported the additional registration data elements proposed in the NPRM. An additional commenter requested that the final rule minimize the number of required registration data elements to provide more flexibility for the reporting of different types of trials. In developing the proposed registration data elements, the Agency carefully considered the statutory provisions and additional requirements in order to carry out those mandates. We believe that the data elements proposed in the NPRM represent a "minimum" data set of the information required to describe and understand key information about a clinical trial. Nevertheless, we have modified some of the proposed definitions and requirements for particular data elements in the final rule in response to public comments as well as on our own initiative (*e.g.,* for clarity or consistency).

§ 11.28(a)—Clinical Trial

Overview of Proposal

Proposed § 11.28(a) specified the data elements that a responsible party would be required to submit to *ClinicalTrials.gov* to register an applicable clinical trial other than a pediatric postmarket surveillance of a device that is not a clinical trial. As we described in the NPRM, the clinical trial registration information data elements are grouped into the four categories used in section 402(j)(2)(A)(ii) of the PHS Act: (1) Descriptive information, (2) recruitment information, (3) location and contact information, and, (4) administrative data. Additional data elements that the Agency proposed were listed in the categories in which they best fit. The proposed clinical trial registration information data elements, grouped by category, were described in detail in the NPRM. See Section IV.B.4(a) of the NPRM for details about the data elements under proposed § 11.28(a) (79 FR 69612).

For each data element defined in proposed § 11.28(a), we describe the following: (1) The proposed definition, (2) any specific public comment(s) we received about the data element and our response(s), and (3) the definition used in § 11.28(a) of the final rule. The information about each data element is ordered by section number as assigned in the codified section of the final rule, which also parallels section 402(j)(2)(A)(ii) of the PHS Act. We note that in the final rule some of the names of the data elements, as well as their numbers, differ from those assigned in the NPRM because of modifications to the data elements, all of which are described in the context of each specific data element. After discussing the last registration data element listed under § 11.28(a) of the final rule (*i.e.,* Responsible Party Contact Information in § 11.28(a)(2)(iv)(F)), we address data elements that were suggested in the public comments but were not added in the final rule.

We have made one overall change to the structure of § 11.28(a) and (b). In light of our determination that the registration requirements that apply to an applicable clinical trial are determined by the date on which the trial is initiated, *i.e.,* the actual Study Start Date, as defined in § 11.10(b)(16) (see discussion below in section IV.F.), we have indicated in both § 11.28(a) and (b) that for applicable clinical trials that must be registered with *ClinicalTrials.gov* as specified in section 402(j)(2)(C) of the PHS Act or § 11.22, the responsible party must submit the information specified in section 402(j)(2)(A)(ii) of the PHS Act or the data elements listed in § 11.28, as applicable.

Based on this modification, § 11.28(a)(1) requires that "[f]or such applicable clinical trials that were initiated before January 18, 2017, the responsible party must submit the information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii))." Section 11.28(a)(2) requires the data elements described below for such applicable clinical trials that are initiated on or after January 18, 2017.

(i) Descriptive Information

(A) *Brief Title.* In § 11.10(b)(1) of the NPRM, Brief Title was defined as "a short title of the clinical trial written in language intended for the lay public, including any acronym or abbreviation used publicly to identify the clinical trial." Section 402(j)(2)(A)(ii)(I)(aa) of the PHS Act specifically requires the submission of a brief title as part of the clinical trial information submitted at registration, but it does not define the term, other than to indicate that the title is "intended for the lay public." As explained in the NPRM, we interpreted this requirement to mean that potential human subjects should be able to understand, from the brief title, the general purpose of the clinical trial and distinguish it from others listed in the data bank. Additionally, based on our experience to date with *ClinicalTrials.gov*, we recognized that acronyms are frequently used to refer to clinical trials (*e.g.,* "ACCORD" for the Action to Control Cardiovascular Risk in Diabetes trial or "STAR*D" for the Sequenced Treatment Alternatives to Relieve Depression trial), and we believe that it is important for such acronyms to be included in the registry to enable users of the data bank to identify clinical trials that they may see referenced in other media (*e.g.,* news reports, journal articles). As such, we considered an acronym used to identify a clinical trial to be part of the brief title (79 FR 69612). We received no comments on this description and therefore maintain the proposed description in the final rule. We note that a Brief Title intended for the lay public should include, where possible, information on the participants, condition being evaluated, and intervention(s) studied.

(B) *Official Title.* In § 11.10(b)(2) of the NPRM, we defined Official Title as "[t]he title of the clinical trial, corresponding to the title of the protocol." As described in the NPRM, while not explicitly required in section 402(j)(2)(A)(ii)(I) of the PHS Act, we used the authority in section 402(j)(2)(A)(iii) of the PHS Act to propose to require a responsible party to submit an official title as part of clinical trial information when registering an applicable clinical trial on *ClinicalTrials.gov*. We expressed our belief that the Official Title will complement the Brief Title that is intended for the lay public by providing a technical title that will help researchers understand the general purpose of the study. The official title would also be helpful in associating the clinical trial on *ClinicalTrials.gov* with information about the clinical trial contained in other sources, such as scientific publications, regulatory submissions, and media reports, which often use the official title of the study protocol (79 FR 69612). We received no comments on this description and therefore maintain the proposed description in the final rule. We note that Official Title is also consistent with the WHO Trial Registration Data Set (version 1.2.1) (WHO data item #10) and ICMJE registration policies, which require the submission of a "scientific title" [Ref. 73, 2].

(C) *Brief Summary.* In § 11.10(b)(3) of the NPRM, Brief Summary was described as "a short description of the clinical trial, including a brief statement of the clinical trial's hypothesis, written in language intended for the lay public." As noted in the NPRM, section 402(j)(2)(A)(ii)(I)(bb) of the PHS Act expressly requires a "brief summary" to be submitted as clinical trial registration information, but it does not define the term other than to indicate that the brief summary is "intended for the lay public" (79 FR 69612). We received no comments on this description and therefore maintain the proposed description in the final rule.

(D) *Primary Purpose.* Under § 11.10(b)(4) of the NPRM, Primary Purpose referred to "the main objective of the intervention(s) being evaluated by the clinical trial." We noted in the NPRM that section 402(j)(2)(A)(ii)(I)(cc) of the PHS Act expressly requires the "primary purpose" of the intervention(s) to be submitted as clinical trial registration information, but it does not define the term (79 FR 69612). We received no comments on this description and maintain the proposed definition in the final rule.

In the NPRM, we stated that we would require a responsible party to provide a response selected from the following set of options: "Treatment," "prevention," "diagnostic," "supportive care," "screening," "health services research," "basic science," "feasibility," or "other" (79 FR 69612) We are modifying the name of one of these options, from "feasibility" to "device feasibility." This change helps responsible parties more easily recognize that the option is intended to be limited to the type of feasibility study of a device that is described as being excluded from the definition of an applicable device clinical trial as specified in section 402(j)(1)(A)(ii) of the PHS Act and defined in § 11.10(a) of this part. "Device feasibility" is distinguished from the general term "feasibility," which is sometimes used in research to describe a study that is performed to determine the practicality of conducting a full clinical trial. We also note that a responsible party may nevertheless voluntarily register a clinical trial that is a feasibility study of a device. Such registration would be a voluntary submission of clinical trial information under section 402(j)(4)(A) of the PHS Act and § 11.60 of the final rule.

In addition, we would like to provide additional clarification for responsible parties regarding the options available under Primary Purpose. These clarifications are as follows: "Treatment" should be selected when one or more interventions are being evaluated for treating a disease, syndrome, or condition; "prevention" should be selected when one or more interventions are being assessed for preventing the development of a specific disease or health condition; "diagnostic" should be selected when one or more interventions are being evaluated for identifying a disease or health condition; "supportive care" should be selected when one or more interventions are being evaluated for maximizing comfort, minimizing side effects, or mitigating against a decline in the subject's health or function; "screening" should be selected when one or more interventions are being assessed or examined for identifying a condition, or risk factors for a condition, in people who are not yet known to have the condition or risk factor; "health services research" should be selected when one or more interventions are being evaluated for the delivery, processes, management, organization or financing of health care; "basic science" should be selected when one or more interventions are being used for examining the basic mechanism of action (*e.g.,* physiology, biomechanics), of an intervention or disease process; "device feasibility" should be selected when a device product is being evaluated for the feasibility of the product or of a test prototype device and not health outcomes; and "other" should be selected when none of the other options apply.

(E) *Study Design.* Proposed § 11.10(b)(5) defined Study Design as "a description of the manner in which the clinical trial will be conducted" and required information about the following important aspects of a clinical trial: Interventional study model, number of arms, arm information, allocation, masking, and whether a single-armed clinical trial is controlled. As we noted in the NPRM, this proposed definition of Study Design, including the key attributes, conforms to ICH Guidelines [Ref. 56] and is consistent with "study type" of the WHO Trial Registration Data Set (version 1.2.1) (WHO data item #15) and ICMJE registration policies [Ref. 2, 73]. Section 402(j)(2)(A)(ii)(I)(dd) of the PHS Act expressly requires "study design" to be submitted as part of clinical trial registration information, but it does not define the term. Because there are many important aspects of a study design, and information about each is relevant to ensuring that the descriptions of study designs are complete and comparable across clinical trials, we proposed to require that several components of study design be submitted, as described below. Although none of these terms is used in section 402(j) of the PHS Act, we pointed out that we believe that each is a key component of study design (79 FR 69613). We received no comments on the overall definition and therefore generally maintain the proposed definition of Study Design in the final rule, with one exception.

The final rule does not include the proposed Single Arm Controlled? data item of the Study Design data element, which was defined in § 11.10(b)(5)(vi) of the NPRM as "[f]or a single-armed clinical trial only, whether or not the clinical trial is controlled, as specified by the protocol or statistical analysis plan." This data item of the Study Design data element was proposed in the NPRM to assist the Agency, responsible parties, and users of the data bank in determining whether a clinical trial with only one arm meets the definition of an applicable clinical trial because it includes a control or is controlled. However, as described in Section IV.A.5, the Agency has clarified its interpretation of "control or controlled" to make clear that all single-arm interventional studies or clinical trials with pre-specified primary or secondary outcome measures are considered to be "controlled" for purposes of this part. As such, the proposed Single Arm Controlled? component of the Study Design data element is not necessary and has been removed from §§ 11.10(b) and 11.22(b) of the final rule.

Interventional Study Model. In § 11.10(b)(5)(i) of the NPRM, this data item was defined as "[t]he strategy for assigning interventions to human subjects." As stated in the NPRM, responsible parties would be required to select an entry from the following limited set of proposed options: "single group" (*i.e.,* clinical trials with a single arm), "parallel" (*i.e.,* participants are assigned to one of two or more groups in parallel for the duration of the study), "cross-over" (*i.e.,* participants receive one of two alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study), and "factorial" (*i.e.,* two or more interventions, each alone and in combination, are evaluated in parallel against a control group). No "other" option was proposed. To address situations in which a clinical trial might use a modified version of one of these models, or the responsible party might wish to provide more information about the specific implementation of the model, we proposed that responsible parties also be able to provide an optional additional free-text description containing more specific details about the interventional study model. We invited public comment on this proposed definition and approach (79 FR 69613). A few commenters recommended that the final rule add an "other" option for Interventional Study Model, with one commenter suggesting "enrichment designs" and "adaptive borrowing of historical data" as examples. We note that these examples do not appear to represent interventional study models that differ conceptually from those proposed in the NPRM. For example, even though "enrichment designs" involve prespecified study periods that allow researchers to select subsets of enrolled participants who are likely to be particularly sensitive to the studied intervention (*e.g.,* to demonstrate the effect of a drug), we believe that the underlying interventional study model involves at least one of the suggested options (*i.e.,* "single-group," "parallel," "cross-over," or "factorial"). The fact that a study involves an enrichment design could be noted in the proposed optional additional free-text description field. The final rule retains the name and definition of Interventional Study Model as proposed in the NPRM. In reviewing this proposed data item, however, we identified two modifications to the set of proposed options. First, based on our experience in operating *ClinicalTrials.gov,* we add the option of "sequential" as we believe that it represents an Interventional Study Model that is fundamentally different from the other options available for selection under Interventional Study Model and is fairly common among drug studies (*e.g.,* dose escalation). Thus, we have added "sequential" as an option under the Interventional Study Model data item; responsible parties would select this option to indicate that groups of participants are assigned to receive interventions based on prior milestones being reached in the study, such as in some dose escalation and adaptive design studies. Second, we have also modified the description of the "cross-over" option to clarify that this term refers to study designs in which participants are assigned to receive one of two (or more) alternative interventions during the initial phase of the study followed by the other intervention(s) during subsequent phase(s) of the study. This modification clarifies that cross-over studies are not restricted to just two interventions, but may involve two (or more) interventions [Ref. 84].

Number of Arms. In § 11.10(b)(5)(ii) of the NPRM, this data item was defined as "[t]he number of arms in the clinical trial. For a trial with multiple periods or phases that have different numbers of arms, the maximum number of arms during any period or phase." We noted that the term "arm" was defined in proposed § 11.10(a) and that some clinical trials contain multiple periods or phases, each of which might use different numbers of arms. We also clarified in the NPRM that we do not consider historical controls to be an "arm" of a clinical trial for the purposes of this part, therefore, they would not be counted in the number of arms (79 FR 69613). One commenter suggested that, for reporting trials with "mutually reporting arms," the maximum number of arms listed should be inclusive of all arms from all periods. This commenter also suggested that historical controls not be counted in the Number of Arms data item of the Study Design data element, which is specified in proposed § 11.28(a)(1)(v) and defined in proposed § 11.10(b)(5)(ii). We interpreted this comment to refer to "mutually exclusive reporting arms," agree with the commenter, and note that the definition in § 11.10(b)(5)(ii) specifies that "[f]or a trial with multiple periods or phases that have different numbers of arms, it means the maximum number of arms during all periods or phases." We also reiterate, as stated in the preamble of the NPRM, that "historical controls are not considered to be an 'arm' of a clinical trial and thus are not counted in the number of arms" (79 FR 69613). After considering this comment, we maintain the proposed definition in the final rule, except the definition clarifies that for a trial with multiple periods or phases that have different numbers of arms, the "number of arms" means the maximum number of arms during "all periods or phases".

Arm Information. In § 11.10(b)(5)(iii) of the NPRM, this data item was defined as "[a] description of each arm of the clinical trial that indicates its role in the clinical trial, provides an informative title, and, if necessary, additional descriptive information to differentiate each arm from other arms in the clinical trial." As stated in the NPRM, responsible parties would be required to select from the following list of options for describing the role of each arm in the clinical trial: "Experimental," "active comparator," "placebo comparator," "sham comparator," "no intervention," or "other." The informative title would consist of a label or short name to identify the arm in the clinical trial record (*e.g.,* the name of the experimental intervention used in the arm or placebo). Additional descriptive information would be required if the informative title does not sufficiently differentiate among arms in the clinical trial (*e.g.,* in a clinical trial that compares two different dosages of the same investigational drug, the descriptive information would have to indicate which is the higher dose arm versus the lower dose arm). Even if the informative title and/or additional descriptive information vary sufficiently among the arms of the clinical trial, responsible parties may voluntarily include additional details about the interventions or the arms in this field (79 FR 69613). We received a few comments about Arm Information. One commenter requested that the final rule clarify that a historical-control arm be considered "other" from the list of options available for Arm Information. Another commenter asked for a way to distinguish between study designs that incorporate "concurrent" and "nonconcurrent" controls, which are described in the preamble discussion of the term "controlled" in the NPRM. As noted in the preamble of the NPRM, we do not consider historical controls or other types of non-concurrent controls to be arms for the purposes of the Number of Arms data item defined in proposed § 11.10(b)(5)(ii) (79 FR 69613). Because Arm Information is used to describe each arm identified by Number of Arms, the need to identify an arm as "historical" or "nonconcurrent" should not arise when submitting Arm Information in *ClinicalTrials.gov.* However, if a responsible party wishes to identify and/or describe a historical or non-concurrent control used in the study, we note that such information could be submitted using an optional data item such as Detailed Description. After consideration of these comments, we generally are maintaining the proposed definition in the final rule. However, we are revising it slightly to specify that if more than one arm is specified for the clinical trial, the responsible party must designate the listed intervention(s) to the arm in which they are administered. Therefore, "arm information" is defined as "[a] description of each arm of the clinical trial that indicates its role in the clinical trial, provides an informative title, and, if necessary, additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial." This designation approach (currently implemented using the "[Arm or Group]/Intervention Cross-Reference" data element) will allow for continuing to display on *ClinicalTrials.gov* arm and intervention information as a table, helping users understand the relationship between arm information and intervention information.

Allocation. In § 11.10(b)(5)(iv) of the NPRM, this data item was defined as "[t]he method by which human subjects are assigned to arms in a clinical trial." As stated in the NPRM, responsible parties would be required to select from the following limited set of options: "randomized" (participants are assigned to intervention groups by chance), or "nonrandomized" (participants are expressly assigned to intervention groups through a non-random method, such as physician choice), or "not applicable" (for a single-arm study). No "other" option was proposed (79 FR 69613). We invited public comment, but did not receive any, therefore, we maintain the proposed definition and approach in the final rule.

Masking. In § 11.10(b)(5)(v) of the NPRM, this data item was defined as "[t]he party or parties, if any, involved in the clinical trial who are prevented from having knowledge of the interventions assigned to individual human subjects." As stated in the NPRM, responsible parties would be required to select from the following limited set of choices for describing which party(ies) is/are masked: "human subject," "care provider," "investigator," and/or an "outcomes assessor" (*i.e.,* the individual who evaluates the outcome(s) of interest). No "other" option was proposed, but responsible parties would have the ability to provide additional, optional free-text information about other parties who may be blinded in the clinical trial (79 FR 69614). We received no comments, however, for clarity, we are adding to the limited menu of choices "no masking" for the responsible party to indicate that the study design does not include masking (*e.g.,* open-label). We otherwise maintain the proposed definition in the final rule.

Single Arm Controlled. In § 11.10(b)(5)(vi) of the NPRM, this data item was defined as "for a single arm clinical trial only, whether or not the clinical trial is controlled, as specified by the protocol or statistical analysis plan." We have deleted this data item in the final rule because the information is no longer necessary to determine whether a clinical trial is "controlled" under the definition in § 11.10(a) and therefore an "applicable drug clinical trial" or "applicable device clinical trial" under the regulations, as discussed in the preamble for § 11.22.

(F) *Study Phase.* In § 11.10(b)(6) of the NPRM, this data element was defined as "for a clinical trial of a drug, the numerical phase of such clinical trial, consistent with terminology in 21 CFR 312.21, or any successor regulation, such as phase 2 or phase 3, and in 21 CFR 312.85, or any successor regulation, for phase 4 studies." Section 402(j)(2)(A)(ii)(I)(ee) of the PHS Act expressly requires, for an applicable drug clinical trial, the "study phase" to be submitted as a clinical trial registration information data element, but it does not define the term. As stated in the NPRM, responsible parties would be required to select one response from a limited list of options that includes phases 1, 2, 3, and 4, consistent with the terminology in 21 CFR 312.21 and 21 CFR 312.85. In addition, responsible parties would be able to select from other options that are commonly used in practice: Phase 1/phase 2 (for trials that are a combination of phases 1 and 2; as discussed previously, phase 1/phase 2 studies are not considered phase 1 studies and may be applicable drug clinical trials) and phase 2/phase 3 (for trials that are a combination of phases 2 and 3). No "other" option was proposed. Although we are aware that the term "phase 0" is used in practice (*e.g.,* to refer to clinical trials that are exploratory in nature and are not designed to evaluate therapeutic or diagnostic intent), any trial that would be referred to as "phase 0" meets the definition of a phase 1 trial under FDA regulations (21 CFR 312.21). Therefore, we did not propose to include "phase 0" as an option for the Study Phase data element, and responsible parties registering a clinical trial that might be referred to as "phase 0" would select "phase 1" for the Study Phase (79 FR 69614). We received no comments on this description and therefore maintain the proposed description in the final rule except that we clarify that "drug" means "drug product." We note that study phases are not intended for use in describing clinical trials of devices; therefore, consistent with section 402(j)(2)(A)(ii)(I)(ee) of the PHS Act, responsible parties for applicable device clinical trials would not be required to submit this data element.

(G) *Study Type.* In § 11.10(b)(7) of the NPRM, we defined this data element as "the type of study for which clinical trial information is being submitted." Section 402(j)(2)(A)(ii)(I)(ff) of the PHS Act expressly requires "study type" to be submitted as clinical trial information at the time of registration, but it does not define the term. Consistent with practice prior to FDAAA, we stated in the NPRM that responsible parties would be required to select one of the following limited set of options: "Interventional," "observational," or "expanded access program." No "other" option was proposed. We expressed our belief that all applicable clinical trials and all other clinical studies that might be registered voluntarily on *ClinicalTrials.gov* could be accurately characterized as either "interventional" or "observational," depending on whether human subjects studied are assigned to interventions based on a research protocol (interventional) or whether patients receive interventions as part of routine medical care, and a researcher studies the effect of the intervention (observational). We indicated that we would consider observational studies to include a wide range of non-interventional studies, including retrospective reviews of patient records or relevant literature (79 FR 69614). (See the elaboration of the terms "applicable device clinical trial" and "applicable drug clinical trial" in Section IV.A.5 of this preamble). We received one comment requesting that we provide clarification by either providing examples or modifying the definition so that it does not use the term being defined. We believe "type of study" in the proposed definition is sufficiently clear, particularly with the three options described for the Study Type data element. In addition, the elaboration of the terms "applicable device clinical trial" and "applicable drug clinical trial" in Section IV.A.5 of this preamble provide further details about interventional and observational studies. We also plan to provide additional guidance, including examples, as needed.

After considering the comments, we maintain the NPRM definition in the final rule, except we clarify that Study Type means "the nature of the investigation or investigational use for which clinical trial information is being submitted, *e.g.,* interventional, observational." We note that a study that is designated "interventional," as that term is defined in this part, may or may not be an applicable clinical trial, depending on whether it meets the other criteria for an applicable clinical trial that are specified in this part. A study that is designated "observational" would be an applicable clinical trial only if it is a pediatric postmarket surveillance of a device product as defined in this part. (See the definition of "pediatric postmarket surveillance of a device product" in § 11.10, the discussion of § 11.28(b), and the discussion of observational studies in Section IV.A.5 of this preamble). Conversely, any applicable clinical trial other than a pediatric postmarket surveillance of a device product must have a Study Type of "interventional." An applicable clinical trial that is a pediatric postmarket surveillance of a device product could have a Study Type of "interventional" or "observational." The term "expanded access" is provided as an option for Study Type because responsible parties who are both manufacturers of an investigational drug product (including a biological product) that is available for expanded access use and sponsors of an applicable clinical trial of the investigational product are required to create an expanded access record for the investigational drug product (including a biological product) if such a record does not already exist at the time the applicable clinical trial is registered. As discussed in section IV.A.5 of this preamble, expanded access use is not considered to be an applicable clinical trial. Therefore, the Study Type for all expanded access use is "expanded access" (see the discussion of § 11.28(c)).

(H) *Pediatric Postmarket Surveillance of a Device Product.* In § 11.10(b)(8) of the NPRM, we defined the Whether the Study is a Pediatric Postmarket Surveillance of a Device data element to mean "for a study that includes a device as an intervention and is a pediatric postmarket surveillance of a device, an affirmation that the study is a pediatric postmarket surveillance of a device." Although this data element is not explicitly listed in section 402(j) of the PHS Act as part of clinical trial information, we proposed it to identify a subset of applicable device clinical trials. As we noted in the NPRM, the term "applicable device clinical trial" is defined, in part, as "a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act" (see section 402(j)(1)(A)(ii)(II) of the PHS Act). A responsible party would be required to provide this data element only if the study is a pediatric postmarket surveillance of a device product; a responsible party would not be required to submit this data element if the device study is not a pediatric postmarket surveillance of a device product (79 FR 69615). We received no comments addressing this data element. In the final rule, we modify the name of the data element to "Pediatric Postmarket Surveillance of a Device Product" to clarify that "device" means "device product" and modify the definition to clarify that the term refers only to "a clinical trial or study that includes a U.S. FDA-regulated device product as an intervention" and is a pediatric postmarket surveillance of a device product "ordered under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 369l)." In the final rule, we also removed from the definition the requirement for an affirmation that the study is a pediatric postmarket surveillance of a device. By indicating that a study is a pediatric postmarket surveillance of a device product, users of the data bank and the Agency will be able to confirm that the study is an applicable device clinical trial. In addition, by combining this information with other submitted clinical trial registration information (*e.g.,* the Study Type data element), the Agency could confirm whether the pediatric postmarket surveillance of a device product is a clinical trial and indicate which other data elements must be submitted at the time of registration. If a pediatric postmarket surveillance of a device product is a clinical trial, the clinical trial registration information data elements set forth in § 11.28(a) will be required to be submitted. If a pediatric postmarket surveillance of a device product is not a clinical trial (*i.e.,* it is a form of observational study, including a retrospective review of patient records or relevant literature), then the clinical trial registration information data elements specified in § 11.28(b) will be required to be submitted.

(I) *Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study.* In § 11.10(b)(9) of the NPRM, we defined this data element as "the name(s) of the disease(s) or condition(s) studied in the clinical trial, or the focus of the clinical trial, using, if available, appropriate descriptors from the NLM's

MeSH controlled vocabulary thesaurus *http://www.nlm.nih.gov/mesh/*, or terms from another vocabulary, such as the SNOMED CT, that has been mapped to MeSH within the UMLS Metathesaurus, *https://uts.nlm.nih.gov.*" As we noted in the NPRM, section 402(j)(2)(A)(ii)(I)(gg) of the PHS Act expressly requires "the primary disease or condition being studied, or the focus of the study" to be submitted as part of clinical trial registration information, but it does not define the term. Section 402(j)(2)(B)(i)(I) of the PHS Act further requires the data bank to be searchable by one or more of eight listed criteria, including "the disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors." To support searching using MeSH descriptors, the primary disease or condition being studied in the clinical trial, or the focus of the study, must be described using either MeSH terminology (*http://www.nlm.nih.gov/mesh/*) or another terminology that has been mapped to MeSH, when available (if the other terminology is mapped to MeSH, the data bank can be searched using MeSH terms and retrieve the correct record(s)) (79 FR 69615). We received no comments on this proposed data element, but we slightly modify the proposed description in the final rule for clarity as follows: "the name(s) of the disease(s) or condition(s) studied in the clinical trial, or the focus of the clinical trial. Use, if available, appropriate descriptors from NLM's Medical Subject Headings (MeSH) controlled vocabulary thesaurus, or terms from another vocabulary, such as the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT), that has been mapped to MeSH within the Unified Medical Language System (UMLS) Metathesaurus." We note that this definition is consistent with "health condition(s) or problem(s) studied" of the WHO Trial Registration Data Set (version 1.2.1) (WHO data item #12) and ICMJE registration policies [Ref. 2, 73].

(J) *Intervention Name(s).* Under § 11.10(b)(10) of the NPRM, Intervention Name was specified as "a brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical trial. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used." Section 402(j)(2)(A)(ii)(I)(hh) of the PHS Act expressly requires "intervention name" to be submitted as part of clinical trial information at the time of registration, but it does not define the term. As we explained in the NPRM, we believe the purpose of this data element is to enable interested parties to readily identify the intervention(s) being studied in each arm of a clinical trial and compare clinical trials by intervention. While some clinical trials compare a single intervention against a placebo, many compare multiple interventions (*e.g.,* a newly developed drug product versus standard treatment, or different dosages of the same drug product). We believe it is important for the names of all interventions studied in a clinical trial to be submitted to the data bank (79 FR 69616). We received no comments on this proposed data element and therefore are maintaining it in the final rule, although we slightly modify its name to "Intervention Name(s)" and specify in the definition that "it" refers to "the intervention" for clarity. Based on our experience in operating *ClinicalTrials.gov*, we recognize that there are inherent difficulties in determining the level of detail that should be required for naming interventions, especially those without non-proprietary (*i.e.,* generic) names [Ref. 23]. We believe that non-proprietary names must be provided for interventions (*e.g.,* drug products (including biological products) and device products) when available. For interventions for which a non-proprietary name is not available, our prior experience suggests that a brief descriptive name can suffice. In either case, additional descriptive information is often needed to distinguish the intervention(s) under study from other, similar interventions used in practice or studied in the same or other clinical trials. Examples of a brief descriptive name or identifier include a chemical name, company code, or serial number. We note that this description of Intervention Name(s) is consistent with the "intervention(s)" of the WHO Trial Registration Data Set (version 1.2.1) (WHO data item #13) and ICMJE registration policies [[Ref. 2, 73].

(K) *Other Intervention Name(s).* In § 11.10(b)(11) of the NPRM, this term was defined as "other current and former name(s) or alias(es), if any, different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention, including, but not limited to, past or present names such as brand name(s), serial numbers, or chemical descriptions." As noted in the NPRM, "other intervention name(s)" is a term that is not used in section 402(j) of the PHS Act, but it is proposed as a data element that responsible parties must submit if the sponsor has used more than one name publicly to identify the intervention under study in a clinical trial. Based on our experience operating *ClinicalTrials.gov*, we are aware that interventions often have multiple names, including, for example, a sponsor code name, brand name(s), or a name or identifier from a standard vocabulary, such as RxNorm for drugs (*http://www.nlm.nih.gov/research/umls/rxnorm/index.html*). Accordingly, providing only a single name for each intervention (as is required under the Intervention Name(s) data element) does not necessarily provide enough information to allow users to find and compare all clinical trials in *ClinicalTrials.gov* that involve a specific intervention, as a different clinical trial with the same intervention may have been registered by another responsible party under a different intervention name. Therefore, we noted that we believe that adding a requirement to submit Other Intervention Name(s) improves and does not reduce the clinical trial information available in the data bank. We also noted that this requirement could mean that, in some circumstances (*e.g.,* when the responsible party is a designated principal investigator), the responsible party would need to communicate with the sponsor or the manufacturer of the intervention(s) to determine whether another name has been used publicly. We indicated that we do not believe such additional communication would be frequent or onerous. The proposal would not have required a responsible party to submit names that have not been used publicly because users of *ClinicalTrials.gov* would be unlikely to search for a clinical trial using such names. We asked for comment on this approach (79 FR 69616) and some commenters addressed the Other Intervention Name(s) data element. A few commenters suggested requiring the use of a universally recognized standard, such as the WHO International Nonproprietary Names (INN) or the FDA unique device identifier (UDI). While we agree that the Other Intervention Name(s) data element includes all standardized names, we note that the data element is not limited to only those intervention names that are compliant with a particular naming standard or convention. As stated in the proposed definition, this data element is intended to broadly capture all "other current and former name(s) or alias(es) . . . that the sponsor has used publicly to identify the intervention." Therefore, we clarify that all names, including internationally recognized standard names, must be submitted for the Other Intervention Name(s) data element.

One commenter indicated that displaying other intervention names would be confusing to the public and suggested that the final rule remove Other Intervention Name(s) as a required data element. Another commenter requested that only the U.S. generic and proprietary names be required for submission. We disagree with both commenters. Because users of *ClinicalTrials.gov* may encounter a number of names for an intervention depending on the source or context (*e.g.,* drug code name), we believe that providing access to all the different public names of an intervention would help users find potentially relevant information. Additionally, requiring responsible parties to provide all public names for an intervention allows the *ClinicalTrials.gov* system to identify and retrieve clinical studies records listing any of the relevant intervention names. After consideration of these comments, we generally maintain this data element as proposed in the final rule. We modify the definition by deleting the phrase "chemical descriptions" to avoid any suggestion that chemical descriptions are required to be submitted. Chemical descriptions are, however, an example of another type of name that would be appropriate to include for Other Intervention Name(s).

(L) *Intervention Description.* In § 11.10(b)(12) of the NPRM, we defined this term to mean "details that can be made public about the intervention, other than the Intervention Name and Other Intervention Name(s), sufficient to distinguish it from other, similar interventions studied in the same or another clinical trial." As we described in the NPRM, while this term is not used in section 402(j) of the PHS Act, we proposed it as an additional data element to be submitted as clinical trial information at the time of registration. Based on prior experience, we recognize that the Intervention Name(s) and Other Intervention Name(s) data elements, whether providing information on brand or non-proprietary names, do not always provide enough information to allow potential human subjects or other *ClinicalTrials.gov* users to differentiate among similar interventions used in different arms of a clinical trial, distinguish the intervention used in one clinical trial from a similar intervention used in another clinical trial, or understand the differences between interventions studied in a clinical trial and those used in routine medical practice. For example, a clinical trial might compare two or more dosages of the same drug or two different clinical trials might examine drug-eluting stents that are similar to those used in standard medical practice. To reduce this ambiguity, additional descriptive information about the intervention is needed, such as information about the dosage, dosage form, frequency of administration, route of administration, and/or duration of administration of a drug, or a general description of the device, including how the device functions; the scientific concepts that form the basis for the device; and the significant physical and performance characteristics of the device, such as its key components and the general types of materials used. The submission of such information would enable users (whether subjects, patients, physicians, researchers, or others) to understand key elements of a clinical trial, and compare information among clinical trials. For these reasons, requiring the submission of an intervention description would improve but not reduce the clinical trial information available in the data bank (79 FR 69616). A few commenters suggested that the Agency consider making optional some of the details required to be submitted for the Intervention Description data element; other commenters recommended that the entire data element be considered optional in the final rule. The reasons provided were that such detailed information may contain confidential commercial information and providing such details would be burdensome. The Agency disagrees with these commenters and continues to believe that users of the public site must be able to understand the interventions that are being compared in a trial and how the comparators differ from each other and/or other similar interventions. For example, the Consolidated Standards Of Reporting Trials (CONSORT) guidelines recommend that each intervention, including control interventions, be described thoroughly so that published studies may be understood more clearly [Ref. 93]. The submission of these details at study registration could also give earlier insight to the problem of study sponsors choosing inapprorpriate comparison groups, which can bias study results [Ref. 94]. As specified in the NPRM, the Agency also believes that sufficiently detailed information could be made public without including information that the sponsor may consider sensitive or proprietary (79 FR 69616). While the final rule retains the name of the proposed data element, we have modified the proposed definition by adding an example for clarity as a second sentence. Thus, the final rule defines the term to mean "details that can be made public about the intervention, other than the Intervention Name(s) and Other Intervention Name(s), sufficient to distinguish it from other, similar interventions studied in the same or another clinical trial. For example, interventions involving drugs may include dosage form, dosage, frequency and duration." We clarify that Intervention Description should be sufficiently detailed to differentiate the specified intervention from other similar interventions, but should not include information that the responsible party cannot make public. For example, if the specific dosage of a drug being studied cannot be divulged, a responsible party could instead indicate whether the dosage is higher or lower than that used in an approved or licensed drug or in another arm of the study. If an experimental device uses different material than previous versions of the device, or than other marketed devices, the responsible party could provide a general description of the new material without including its specific formulation.

(M) *Intervention Type.* In § 11.10(b)(13) of the NPRM, Intervention Type was defined as "for each intervention studied in the clinical trial, the general type of intervention." As we pointed out in the NPRM, section 402(j)(2)(A)(ii)(I)(hh) of the PHS Act expressly requires "intervention type" to be submitted as part of clinical trial information at the time of registration, but it does not define the term. We further proposed that responsible parties would be required to select one of the following options for each intervention studied: "drug" (including placebo), "device" (including sham), "biological/vaccine," "procedure/surgery," "radiation," "behavioral" (*e.g.,* psychotherapy, lifestyle counseling), "genetic" (including gene transfer, stem cell and recombinant DNA), "dietary supplement" (*e.g.,* vitamins, minerals), "combination product" (combining a drug and device, a biological product and device; a drug and biological product; or a drug, biological product, and device), "diagnostic test" (*e.g.,* imaging, in-vitro), and "other." We noted that when the intervention used is a combination product (*e.g.,* drug-eluting stent), the responsible party must select "combination product" as the Intervention Type (79 FR 69617). We received one comment requesting clarification by either providing examples or modifying the definition so that it does not use the term being defined. We believe "type of intervention" in the proposed definition is sufficiently clear, particularly with the options described for the Intervention Type data element. We also plan to provide additional guidance as needed.

After considering the comments, we maintain the NPRM definition in the final rule, except that we add "*e.g.*, drug, biological/vaccine, or device" as examples for clarification. Note that, as specified in § 11.28(a)(2)(i)(M) of the final rule, selection of an Intervention Type is required for each intervention studied in each arm of the clinical trial. Some clinical trials will therefore include multiple intervention types. As discussed in Section IV.B.2 of this preamble, a clinical trial that studies a drug and a device as separate, independent interventions would list both "drug" and "device" as Intervention Types and may meet the definitions of both an applicable device clinical trial and an applicable drug clinical trial. If the U.S. FDA-regulated device product studied in such an applicable clinical trial is not approved or cleared by FDA for any use, we would not post clinical trial registration information for that applicable clinical trial prior to the date of approval or clearance of the device product, consistent with § 11.35(b)(2)(i), unless the responsible party indicates, pursuant to § 11.35(b)(2)(ii), that it authorizes such posting. In addition, if the Intervention Type is specified as a "drug," "biological/vaccine," or "device," but both the Studies a U.S. FDA-regulated Device Product and Studies a U.S. FDA-regulated Drug Product data elements are specified as "no," the clinical trial would not be an applicable clinical trial under the definition in § 11.10(a). For this reason, we note that the Intervention Type data element is not used in determining whether a clinical trial is an applicable clinical trial as specified in § 11.22(b).

(N) *Studies a U.S. FDA-regulated Device Product.* In § 11.10(b)(39) of the NPRM, we defined this data element to mean "a clinical trial that studies a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act." As we described in the NPRM, although section 402(j) of the PHS Act does not explicitly require submission of such a clinical trial registration information data element, we proposed to require such a data element using our authority under section 402(j)(2)(A)(iii) of the PHS Act, to assist responsible parties, users of *ClinicalTrials.gov,* and the Agency in determining whether a clinical trial is an applicable device clinical trial, using the approach specified in proposed § 11.22(b)(1). As specified in the elaboration of the definition of an "applicable device clinical trial" in Section IV.A.5 of this preamble, one criterion for an applicable device clinical trial is that the clinical trial studies a device product "subject to section 510(k), 515, or 520(m) of the [FD&C Act]." It is possible that a clinical trial with an Intervention Type of "device" would not be an applicable device clinical trial because the device is not subject to section 510(k), 515, or 520(m) of the FD&C Act. Conversely, it is possible that a clinical trial could be an applicable device clinical trial even if none of the specified Intervention Types is a "device." For example, a clinical trial for which a responsible party indicates the Intervention Type is "radiation," "genetic," or "procedure" could in fact be an applicable device clinical trial studying a device product subject to section 510(k), 515, or 520(m) of the FD&C Act (*e.g.*, an x-ray device, a genetic test, or a surgical instrument). If the responsible party has obtained an IDE and submitted an IDE number to *ClinicalTrials.gov,* the clinical trial is considered an applicable device clinical trial as defined in this part. If the responsible party does not submit an IDE number, however, ambiguity would arise because the lack of an IDE number (or an IDE) does not necessarily indicate that a clinical trial is not an applicable device clinical trial. We proposed requiring the Studies an FDA-regulated Device data element in the NPRM to avoid this ambiguity and help ensure that applicable clinical trials can be properly identified. Consistent with the elaboration of the term applicable device clinical trial in Section IV.A.4 of this preamble, we interpreted this definition to mean that the clinical trial studies a device that would require any of the following before it may be legally marketed in the United States: (1) A finding of substantial equivalence under section 510(k) of the FD&C Act, (2) an order under section 515 of the FD&C Act approving a premarket approval application (PMA) for the device, or (3) an HDE under section 520(m) of the FD&C Act. We believe that submission of this information would improve and not reduce the clinical trial information submitted at the time of registration by making it clear to the responsible party, the Agency, and users of *ClinicalTrials.gov* whether a clinical trial without an IDE studies an FDA-regulated device. This information would, in turn, be used in determining whether a clinical trial meets the definition of an applicable device clinical trial, following the approach specified in proposed § 11.22(b)(1). We also noted that, to reduce the data entry burden on responsible parties, *ClinicalTrials.gov* could automatically pre-populate this data field to indicate "yes" if a responsible party submits an IDE number as part of the FDA IND or IDE Number data element specified in proposed § 11.10(b)(35) (79 FR 69617).

We received no comments addressing the proposed data element and therefore retain the proposed definition in the final rule, except that the definition clarifies that "device" is "device product" and includes the applicable U.S.C. statutory citations in the final rule. The name has also been changed from the proposed "Studies an FDA-regulated Device" to "Studies a U.S. FDA-regulated Device Product" in the final rule for clarity. We also note that we are aware that device products may be used in clinical trials even though they are not the intervention studied in the clinical trial or the experimental variable of interest in the study. For example, clinical trials of procedures involving surgical device products may not be designed to study the effect of those device products. Therefore, when considering whether a clinical trial Studies a U.S. FDA-regulated Device Product a responsible party should consider whether (a) the study is designed to examine the effect or performance of an FDA-regulated device product or differences in the intended use, for example, variations in frequency of use, method of administration, design specifications, and other characteristics (*e.g.*, used in one or more, but not all, arms in a multi-arm study); and/or (b) at least one pre-specified primary or secondary outcome measure reflects a characteristic, effect, or performance of an FDA-regulated device product (*e.g.*, need for replacement or maintenance of the device). As described in the preamble discussion of an applicable device clinical trial in § 11.10(a), a clinical trial of a combination product with a device primary mode of action that otherwise meets the definition of an "applicable clinical trial" will be considered an applicable device clinical trial. We note that for such trials, the responsible party must indicate that the trial Studies a U.S. FDA-regulated Device Product.

(O) *Studies a U.S. FDA-regulated Drug Product.* In § 11.10(b)(40) of the NPRM, we defined this data element to mean "a clinical trial that studies a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Services Act." As we described in the NPRM, section 402(j) of the PHS Act does not explicitly require submission of such a clinical trial registration information data element. We proposed to require this data element, however, using our authority under section 402(j)(2)(A)(iii) of the PHS Act to assist responsible parties, users of *ClinicalTrials.gov*, and the Agency in determining whether or not a clinical trial is an applicable drug clinical trial using the approach specified in proposed § 11.22(b)(2). As specified in the elaboration of the definition of an "applicable drug clinical trial" in Section IV.A.5 of this preamble, one criterion for an applicable drug clinical trial is that the clinical trial studies a drug "subject to section 505 of the [FD&C] Act or [a biological product subject] to section 351 of [the PHS] Act." We noted that it is possible that a clinical trial with an Intervention Type of "drug" or "biological/vaccine" would not be an applicable drug clinical trial because the drug product is not subject to section 505 of the FD&C Act (*e.g.,* a non-prescription drug product that is marketed under an over-the-counter drug monograph) and/or the biological product is not subject to section 351 of the PHS Act. Conversely, we indicated that it is possible that a clinical trial could be an applicable drug clinical trial even if the responsible party does not select "drug" or "biological/vaccine" as the Intervention Type. A clinical trial for which the responsible party indicates the Intervention Type to be "dietary supplement" or "genetic" or "procedure" could in fact be an applicable drug clinical trial studying a drug product subject to section 505 of the FD&C Act or a biological product subject to section 351 of the PHS Act. For example, a product otherwise marketed as a dietary supplement could be studied for the treatment of cancer, or a genetic trial could study a gene therapy. If the responsible party has obtained an IND and submitted an IND number to *ClinicalTrials.gov*, the clinical trial would generally be an applicable drug clinical trial as defined in the NPRM. If the responsible party does not submit an IND number, however, ambiguity would arise because the lack of an IND number (or an IND) does not necessarily indicate that a trial is not an applicable drug clinical trial. To avoid this ambiguity and help ensure that applicable clinical trials can be properly identified, we proposed to require a responsible party to specifically indicate whether a clinical trial studies an FDA-regulated drug by submitting the Studies an FDA-regulated Drug data element. Consistent with the elaboration of the term "applicable drug clinical trial" in the NPRM, we interpreted this definition to mean that the clinical trial studies a drug that is the subject of an approved NDA or BLA or that would require an approved NDA or BLA to be legally marketed in the United States. We noted in the NPRM our belief that submission of this information would improve, and not reduce, the clinical trial information submitted at the time of registration by making it clear to the responsible party, the Agency, and users of *ClinicalTrials.gov* whether a clinical trial without an IND studies an FDA-regulated drug product (including a biological product). This information would, in turn, be used in determining whether a clinical trial meets the definition of an "applicable drug clinical trial," following the approach specified in proposed § 11.22(b)(2). To reduce the data entry burden on responsible parties, we noted that *ClinicalTrials.gov* could automatically pre-populate this data field to indicate "yes" if a responsible party submits an IND number as part of the FDA IND or IDE Number data element specified in proposed § 11.10(b)(35) (79 FR 69618).

We received no comments addressing the proposed data element and therefore retain the proposed definition in the final rule, except that the definition clarifies that "drug" is "drug product" and includes the applicable U.S.C. statutory citations in the final rule. However, the name has been changed from "Studies an FDA-regulated Drug" in the NPRM to "Studies a U.S. FDA-regulated Drug Product" in the final rule for clarity. We also note that we are aware that a clinical trial may include an FDA-regulated drug product even though the drug product is not a variable of interest. For example, a clinical trial of a device product may involve the surgical insertion of the device product under anesthesia, but the anesthesia drug product is not studied in the clinical trial. In determining whether a clinical trial studies a U.S. FDA-regulated drug product, a responsible party should consider whether (a) the clinical trial is designed to examine the effect of the FDA-regulated drug product(s) or of differences in the intended use, including differences in dosing, frequency of use, or route of administration; and/or (b) at least one of the pre-specified primary or secondary outcome measures reflects a characteristic or effect of the FDA-regulated drug product(s). As described in the preamble discussion of applicable drug clinical trial in § 11.10(a), a clinical trial of a combination product with a drug primary mode of action will be considered an applicable drug clinical trial. We note that for such trials, the responsible party must indicate that the trial Studies a U.S. FDA-regulated Drug Product.

(P) *Device Product Not Approved or Cleared by U.S. FDA.* In proposed § 11.10(b)(14), we defined U.S. FDA Approval, Licensure, or Clearance Status to mean "for each drug or device studied in the clinical trial, whether that drug or device is approved, licensed, or cleared by the U.S. Food and Drug Administration for any use." Although section 402(j) of the PHS Act does not explicitly require that such a data element be submitted as part of clinical trial information, we proposed it to help ensure that the data bank operates in compliance with statutory requirements, *e.g.,* knowledge of the approval or clearance status of a device is necessary to determine when clinical trial registration information submitted for an applicable device clinical trial may be posted publicly in the data bank (see section 402(j)(2)(D)(ii) of the PHS Act.) We indicated that this information would also be helpful for users of *ClinicalTrials.gov*, including potential participants, who may wish to know whether or not the product(s) under study have been approved, licensed, or cleared for the use studied in the clinical trial. Requiring submission of the approval, licensure, or clearance status for each drug or device studied in an applicable clinical trial would therefore improve and not reduce the clinical trial information available in the data bank, consistent with section 402(j)(2)(A)(iii) of the PHS Act for proposed modifications to clinical trial registration information. We also stated in the NPRM that we would require responsible parties to select a response from the following limited list of choices: "for studied use(s)" (the drug, biological product, or device is approved, licensed, or cleared for the use studied in the clinical trial), "for other use(s)" (the drug, biological product, or device is approved, licensed, or cleared for use(s) other than those studied in the clinical trial, *e.g.,* the clinical trial studies a new use of the product), or "No" (the product has not been approved, licensed, or cleared for any use). No "other" option was proposed, but a responsible party would also be able to provide additional, optional free-text information to further describe the approval, licensure, or clearance status (*e.g.,* to indicate that the product has been approved in another dose or dosage form, or to list the indications for which it has been approved). We invited public comment on whether the set of proposed options is sufficient (79 FR 69618).

Some commenters addressed the proposed U.S. FDA Approval, Licensure, or Clearance Status data element. One commenter requested clarification on whether more information than the FDA approval, licensure, or clearance status would be required for this data element, while another commenter recommended that the Agency itself submit information for this data element. In reviewing these comments and assessing ways to reduce reporting burden where possible, we reconsidered the proposed approach of requiring the FDA approval, licensure, or clearance status information for each product studied in the clinical trial. A separate data element about the approval, licensure, or clearance status for each drug product, biological product, or device product studied in an applicable clinical trial is, for the most part, not necessary to implement these regulations, because that information is provided via other data elements, when necessary. For example, responsible parties will notify the Agency that they are seeking "initial" approval, licensure or clearance of a product or approval, licensure, or clearance of a "new use" for a product studied in the trial by submitting a certification for delayed submission of results information in accordance with § 11.44(b) and 11.44(c), respectively. A key exception, however, is the need for *ClinicalTrials.gov* to identify applicable device clinical trials that study a device product that has not been previously approved or cleared in order to delay public posting of the submitted clinical trial registration information, as specified in § 11.35(b)(2)(i). Therefore, the final rule replaces the proposed U.S. FDA Approval, Licensure, or Clearance Status data element with the Device Product Not Approved or Cleared by U.S. FDA data element in § 11.28(a)(2)(i)(P), which is defined in § 11.10(b)(14) of the final rule to mean "that at least one device product studied in the clinical trial has not been previously approved or cleared by FDA for one or more uses." As discussed below, this data element must be updated not later than 15 calendar days after a change in approval or clearance status of one or more of the device products studied in the applicable clinical trial.

A responsible party would only be required to complete this data element for a record in which "Yes" is selected as the response to the Studies a U.S. FDA-regulated Device Product data element in § 11.28(a)(2)(i)(N). We would require responsible parties to select a response from the following limited list of choices: "Yes" (at least one studied FDA-regulated device product has not been previously approved or cleared by FDA for one or more uses and therefore the applicable device clinical trial may be subject to the delayed posting requirements specified in § 11.35(b)(2)(i)) or "No" (all studied FDA-regulated device products have been previously approved or cleared by FDA for at least one use and therefore the applicable device clinical trial is not subject to the delayed posting requirement specified in § 11.35(b)(2)(i)).

We included the word "product" in the name of the Device Product Not Approved or Cleared by U.S. FDA data element in § 11.28(a)(2)(i)(P) to clarify that, as explained in Section IV.C.3, the Agency in the final rule is focusing on the device "product" rather than the device "type" when determining which PMA approvals or 510(k) clearances are considered "initial" approvals or clearances versus approvals or clearances of a "new use." For example, with respect to 510(k) clearances, the Agency is interpreting "initial clearance" in the final rule to pertain to the clearance of a manufacturer's original 510(k) submission for a particular device product whereas "clearance of a new use" of a device pertains to the clearance of the same manufacturer's subsequent 510(k) submission for an additional use for the same device product. The term "manufacturer" means a manufacturer who is the sponsor of the applicable clinical trial.

This interpretation subjects clinical trial registration information for more devices to delayed posting under section 402(j)(2)(D)(ii)(I) of the PHS Act as compared with the NPRM approach, because each individual device manufacturer seeking initial clearance of its device product would be subject to delayed posting of its clinical trial registration information, as specified in § 11.35(b)(2)(i) of the final rule, rather than only the first manufacturer to obtain clearance for the device type. Consistent with this interpretation, under the definition of "Device Product Not Approved or Cleared by U.S. FDA," if a manufacturer's original 510(k) submission for its particular device product has not been previously cleared, then that manufacturer's device product would be considered a "device product not cleared by FDA," even if another manufacturer has already obtained 510(k) clearance of its device product within the same product type.

A few commenters suggested that the final rule include an option for providing information about the use for which the product has been approved, and additional commenters requested the addition of the option "Approved but not for use being studied." We agree that choices other than the three proposed in the NPRM (*i.e.,* "for studied uses(s)," "for other uses," and "no") could provide other useful information about a product's approval status. However, because of changes to the data element in the final rule (to indicate "whether at least one device product studied in the clinical trial has not been previously approved or cleared by FDA for one or more uses," as described below) the options proposed by the commenters for specifying the approval, licensure, or clearance status of each studied drug product or device product will no longer be necessary. Another commenter requested that the final rule require the submission of information about the particular approved, licensed, or cleared uses of each product using a standardized terminology to ensure the usefulness and consistency of this information within and across study records. We note that section 402(j)(3)(A)(ii) of the PHS Act requires *ClinicalTrials.gov* to link to information about approved, licensed, or cleared products available on the FDA Web site (*e.g.,* FDA advisory committee meeting summaries, public health advisories, and action package for approval documents) as well as citations from the published literature and structured product labels in NLM's PubMed (*http://www.ncbi.nlm.nih.gov/pubmed/*) and DailyMed (*https://dailymed.nlm.nih.gov/dailymed/*) databases, respectively.

(Q) *Post Prior to U.S. FDA Approval or Clearance.* This data element was neither specified as clinical trial registration information in section 402(j)(2)(A)(ii) of the PHS Act nor proposed in the NPRM. We define the term in § 11.10(b)(40) of the final rule to mean "for an applicable device clinical trial of a device product that has not been previously approved or cleared, the responsible party indicates to the Director that it is authorizing the Director, in accordance with § 11.35(b)(2)(ii), to publicly post its clinical trial registration information, which would otherwise be subject to delayed posting, as specified in § 11.35(b)(2)(i), prior to the date of FDA approval or clearance of its device product." We also list the data element as a component of clinical trial registration information in § 11.28(a)(2)(i)(Q) in accordance with the statutory authority in section 402(j)(2)(A)(iii) of the PHS Act, which permits the Secretary to "modify the requirements for clinical trial [registration] information" by regulation, provided that "such a modification improves and does not reduce such clinical trial information." The Post Prior to U.S. FDA Approval or Clearance data element is needed to allow a responsible party for an applicable clinical trial of a device product that is unapproved or uncleared to indicate to the Director that it is authorizing the Director to publicly post on *ClinicalTrials.gov* its clinical trial registration information, which would otherwise be subject to delayed posting as specified in § 11.35(b)(2)(i), prior to the date of approval or clearance of the product, pursuant to § 11.35(b)(2)(ii). Otherwise, all such trials are subject to the posting deadline specified in § 11.35(b)(2)(i), which states that the Director will post publicly the clinical trial registration information, except for certain administrative data, not earlier than the date of FDA approval or clearance of the device product (see the preamble discussion of § 11.35 for further details). To reduce data submission burden, a responsible party would have this option if the Studies a U.S. FDA-regulated Device Product and the Device Product Not Approved or Cleared by U.S. FDA data elements indicate that at least one studied device product has not been approved or cleared by FDA.

(R) *Product Manufactured in and Exported from the U.S.* In § 11.10(b)(15) of the NPRM, we proposed the following definition for the Product Manufactured in the U.S. data element: "For a drug or device studied in a clinical trial, whether or not the drug or device is manufactured in the U.S. or one of its territories." Although section 402(j) of the PHS Act does not explicitly require that such a data element be submitted as part of clinical trial information, we proposed to include it, using our authority under section 402(j)(2)(A)(iii) of the PHS Act to allow users to determine whether a registered clinical trial is an applicable clinical trial. As explained in the definitions of "applicable device clinical trial" and "applicable drug clinical trial," the NPRM noted that even if a clinical trial is being conducted entirely outside of the United States or one of its territories, it is still an applicable clinical trial when the drug product or device product is manufactured in the United States or one of its territories. We noted that a drug product or device product manufactured in the United States or one of its territories is subject to regulation under the FD&C Act, even if it is exported for study in another country (see, for example, 21 CFR 312.110 and section 802 of the FD&C Act). Therefore, we proposed that information indicating whether each intervention studied in a clinical trial is manufactured in the United States or one of its territories would be essential in some situations for determining whether such trial is subject to FDA jurisdiction and meets the definition of an "applicable clinical trial." We indicated that including this information in the data bank would improve and not reduce clinical trial information by publicly providing data necessary to determine whether such trial is an applicable clinical trial (79 FR 69618). We did not receive any public comments on this proposed data element, but we have modified the definition in the final rule. In assessing ways to reduce reporting burden where possible, we reconsidered the proposed requirement for United States product manufacturing information for each drug product (including a biological product) or device product studied in a clinical trial. To determine whether a clinical trial that is not conducted under an IND or IDE and that does not have any study facilities in the United States or its territories meets the definition of an "applicable clinical trial," the Agency, responsible parties, and the public only need information about whether at least one drug product (including biological product) or device product was manufactured in the United States and exported for research. Therefore, we renamed the data element "Product Manufactured in and Exported from the U.S." in § 11.28(a)(2)(i)(R) to clarify that the intent is to identify a U.S.-manufactured product that is exported for research purposes. Additionally, we clarify that "drug" means "drug product" and "device" means "device product." In § 11.10(b)(15) of the final rule, we define this data element to mean "that any drug product (including a biological product) or device product studied in the clinical trial is manufactured in the United States or one of its territories and exported for study in a clinical trial in another country." To reduce data submission burden, a responsible party would be required to complete this data element only if the entry submitted for the U.S. Food and Drug Administration IND or IDE Number data element indicates that there is no IND or IDE for the clinical trial, and the entry(ies) for the Facility Information data element include no facility locations in the United States or its territories.

(S) *Study Start Date.* In § 11.10(b)(16) of the NPRM, we defined Study Start Date to mean: "the estimated date on which the clinical trial will be open to enrollment of human subjects. If the clinical trial has enrolled the first human subject, the actual date on which the first human subject was enrolled." Section 402(j)(2)(A)(ii)(I)(ii) of the PHS Act expressly requires "study start date" to be submitted as clinical trial information at the time of registration, but it does not define the term. Section 402(j)(2)(C)(ii) of the PHS Act and proposed § 11.24(a) generally required that clinical trial registration information be submitted to *ClinicalTrials.gov* not later than 21 calendar days after the first human subject is enrolled in the clinical trial. In practice, however, many responsible parties submit clinical trial registration information to *ClinicalTrials.gov* before the first subject is enrolled. In some cases, at the time the clinical trial is registered, the responsible party may not have information about when the first subject will be enrolled or was enrolled (*e.g.,* in a large multi-site trial) but may only know when the clinical trial was or will be opened for enrollment. To account for these potential scenarios, we proposed that responsible parties be required to provide an estimated study start date (*i.e.,* the estimated date on which the clinical trial will be open to enrollment of human subjects), unless and until the responsible party knows the actual study start date (*i.e.,* the actual date on which the first human subject is enrolled). The responsible party would be required to update the Study Start Date data element to reflect the actual study start date not later than 30 calendar days after the first human subject is enrolled, consistent with proposed § 11.64. We suggested in the NPRM that providing the estimated study start date to the public, even before the first subject is enrolled, has important benefits to potential human subjects because it will allow them to know when a clinical trial will likely be open to enrollment. We clarified that the Study Start Date must include the day, month, and year (79 FR 69619).

We received comments on this definition. Several commenters requested that we change the term "Study Start Date" to "Date of First Enrolled Participant" to avoid confusion with other contexts, such as those related to human subjects protection and IRB oversight, in which the study start date is considered to be when the study is first approved by the IRB and is recruiting. Another comment stated that the WHO Trial Registration Data Set, defines study start date as the date of first enrollment. One commenter requested that we change the definition of "Study Start Date" to "date of first enrollment" for consistency with these other policies. Another comment asserted that ICMJE, WHO, FDA, and EMA consider the study start date to be the "First-Patient-First-Visit," which is the first participant's anticipated or actual enrollment date, rather than when the trial is first opened to enrollment. Another commenter acknowledged that our definition requires the Study Start Date to be updated with the "First-Patient-First-Visit" (*i.e.,* actual enrollment date) but stated that the other, estimated date on which the clinical trial will be open to enrollment is inconsistent with these other study start date definitions. The commenter requested that we change the definition to "First-Patient-First-Visit." After considering these comments, we maintain the proposed definition for Study Start Date in § 11.10(b)(16) of the final rule, with slight modifications for consistency of phrasing with similar data elements concerning when the responsible party would update the data element with the actual enrollment date. As such, we define Study Start Date as "the estimated date on which the clinical trial will be open for recruitment of human subjects, or the actual date on which the first human subject was enrolled." If the estimated date is used, the responsible party must update the Study Start Date data element to the actual date on which the first human subject was enrolled. We also decline to define Study Start Date as only the "First-Patient-First-Visit" or actual enrollment date. The definition already incorporates the actual enrollment date, which the responsible party will use when the first subject has been enrolled. By including the date when recruitment opens and the date of first enrollment, we believe the definition maintains consistency with prior practice at *ClinicalTrials.gov* and addresses commenters' request to document the date of first human subject enrollment as in the WHO Trial Registration Data Set. As stated in the NPRM, we believe that providing the estimated study start date to the public, even before the first subject is enrolled, has important benefits to potential human subjects because it will provide them with the date on which a clinical trial will likely be open to enrollment. To minimize the burden associated with this requirement and to reflect that it is an estimated date, the date may be provided as "month, year" when estimated and updated to "day, month, year" when actual. We also note that, as discussed above, the final rule modifies the proposed definition of "enroll or enrolled," a component of the definition of Study Start Date (see Section IV.A.5 of this preamble). We note that if a clinical trial is registered with an estimated study start date but the clinical trial is then halted before enrolling the first subject (*e.g.,* because of difficulties in recruitment or loss of funding), the responsible party would not be expected to update the study start date. Instead, the responsible party would be expected to update the Overall Recruitment Status data element defined in § 11.10(b)(25) and specified in § 11.28(a)(2)(ii)(E) to indicate that the clinical trial has been "withdrawn," as such term is used for the purpose of this regulation, and update the Why Study Stopped data element defined in § 11.10(b)(26) and specified in § 11.28(a)(2)(ii)(F).

We note that, as stated in § 11.22(a)(3), an applicable clinical trial, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, is considered to be initiated on the date on which the first human subject is enrolled. Therefore, we consider the actual Study Start Date to be the date of initiation for an applicable clinical trial other than a pediatric postmarket surveillance of a device product that is not a clinical trial.

(T) *Primary Completion Date.* In § 11.28(a)(1)(xiv) of the NPRM, we proposed that when registering a clinical trial, a responsible party must submit the Completion Date for the clinical trial, which was defined in proposed § 11.10(b)(17) of the NPRM as "the estimated completion date. Once the clinical trial has reached the completion date, the responsible party must update the Completion Date data element to reflect the actual completion date." Section 402(j)(2)(A)(ii)(I)(jj) of the PHS Act requires the responsible party to submit information on the "expected completion date" of an applicable clinical trial when registering a clinical trial. We noted in the NPRM that the public availability of information about the expected primary completion date (*i.e.,* the expected completion date) is important for an ongoing clinical trial because it provides an indication of the relative progress of the clinical trial and the expected date on which results information may be submitted to the data bank because section 402(j)(3)(c)(i) of the PHS Act requires that, in general, clinical trial results information be submitted not later than 1 year after the earlier of the estimated completion date of the applicable clinical trial or the actual completion date of the applicable clinical trial. We note that certain exceptions apply to this general deadline for the submission of clinical trial results information (see discussion of § 11.44). In addition, we interpreted the phrase "estimated completion date," as such term is used in section 402(j)(3)(c)(i)(I) of the PHS Act, to have the same meaning as "expected completion date," as such term is used in section 402(j)(2)(A)(ii)(I)(jj) of the PHS Act, because both indicate the date on which the responsible party anticipates that the clinical trial will be completed in relation to the primary outcome measures. In addition, we expressed our belief that it is important for users to have information about the actual completion date of a clinical trial, so they know when clinical trial results information would ordinarily be due under section 402(j)(3)(c)(i) of the PHS Act and proposed § 11.44(a), absent certain specified circumstances in which the submission of clinical trial results information may be delayed. Because clinical trial results information generally is required under section 402(j)(3)(c)(i) of the PHS Act and under proposed § 11.44 to be submitted not later than 1 year after the estimated or actual completion date, whichever is earlier, we expressed our belief that it is important for the Completion Date data element to be updated promptly after the completion date is reached. We proposed to require the responsible party to take the following steps with regard to the Completion Date data element: (1) Provide a reasonable estimated completion date at the time of registration; (2) update the estimated completion date at least once every 12 months during the course of the clinical trial, in accordance with proposed § 11.64(a)(2), if the estimate changes; and (3) update the Completion Date information to indicate the actual completion date not later than 30 calendar days after the clinical trial reaches its completion date, in accordance with proposed § 11.64(b)(1)(viii) (79 FR 69619).

Commenters expressed concern about possible confusion and misinterpretation among responsible parties and the public resulting from the proposed data element name and uniformly suggested replacing "completion date" with "primary completion date" or "primary outcome measure completion date," with several noting that *ClinicalTrials.gov* has used the term "primary completion date" since the enactment of FDAAA. We agree with these comments and note that the Primary Completion Date data element was created in response to section 402(j) of the PHS Act to avoid confusion with the Study Completion Date data element, which existed prior to the law and is currently an optional data element. Furthermore, the final rule in § 11.28(a)(2)(i)(U) adds the Study Completion Date data element as a component of clinical trial registration information. In response to these comments and taking into consideration statutory requirements, we rename the Completion Date data element "Primary Completion Date" in § 11.28(a)(2)(i)(T) of the final rule and use the term "Primary Completion Date" throughout the final rule for clarity. Primary Completion Date is defined in § 11.10(b)(17) of the final rule to mean "the estimated or actual primary completion date. If an estimated primary completion date is used, the responsible party must update the Primary Completion Date data element once the clinical trial has reached the primary completion date to reflect the actual primary completion date." We also note that the term "completion date" in § 11.10(a) of the final rule states, in part, that "[f]or purposes of this part, completion date is referred to as 'primary completion date.'"

(U) *Study Completion Date.* This data element was neither specified as clinical trial registration information in section 402(j)(2)(A)(ii) of the PHS Act nor proposed in the NPRM. We define the term "study completion date" in § 11.10(a) of the final rule to mean "for a clinical trial, the date the final subject was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (*e.g.,* last subject's last visit), whether the clinical trial concluded according to the pre-specified protocol or was terminated." The final rule also lists Study Completion Date as a required registration data element under § 11.28(a)(2)(i)(U) and specifies the data element definition in § 11.10(b)(41) as "the estimated or actual study completion date. Once the clinical trial has reached the study completion date, the responsible party must update the Study Completion Date data element to reflect the actual study completion date in accordance with § 11.64(a)(1)(ii)(J)." We have included the study completion date as a component of clinical trial registration information in accordance with the statutory authority in section 402(j)(2)(A)(iii) of the PHS Act, which permits the Secretary to "modify the requirements for clinical trial [registration] information" by regulation, provided that "such a modification improves and does not reduce such clinical trial information." We believe that Study Completion Date is helpful to indicate to the Agency, responsible parties, and the public when all primary and secondary outcome measures and collection of all adverse event information, as specified in the protocol, will be completed and when final data collection for all primary and secondary outcomes and all adverse events has occurred. Some commenters requested that a mechanism be included in the PRS to make clear to responsible parties when they have fulfilled all obligations to update the study record as specified in proposed § 11.64(a)(3) and that no further updates are required. Several other commenters suggested that "completion date," defined in proposed § 11.10(a), be redefined to mean "final visit/final patient" or "final visit/final patient for all outcome measures." Following an internal review of the proposed rule, we also note that while proposed § 11.44(d) described the procedure for submitting partial results information, it did not specify how to determine when the responsible party's obligation under subpart C is fulfilled. While the Study Completion Date does not specify when these obligations are fulfilled per se, it does provide the minimum amount of information needed to make such a determination based on when all of the data for a trial is to be collected. Note that § 11.64(a)(1)(ii)(J) of the final rule requires the responsible party to update the Study Completion Date within 30 calendar days after the clinical trial reaches its actual study completion date.

(V) *Enrollment.* We defined this data element in § 11.10(b)(18) of the NPRM as "the estimated total number of human subjects to be enrolled or target number of human subjects in the clinical trial." Section 402(j)(2)(A)(ii)(I)(kk) of the PHS Act expressly requires submission of "the target number of subjects" to be enrolled in an applicable clinical trial, but this phrase is not defined. We expressed our belief that this data element is intended to describe the intended or estimated size of the clinical trial, in terms of the estimated total number of human subjects (including healthy volunteers) or target number of human subjects to be enrolled in the clinical trial. We therefore proposed in § 11.28(a)(1)(xx) of the NPRM to require the submission of enrollment information at the time of registration (79 FR 69620). We received a few comments addressing the Enrollment data element. One commenter suggested that the final rule require submission of information about target enrollment goals by gender, age, and race/ethnicity during registration but did not provide any specific justification or evidence that such information is necessary for registration. We note that the clinical trials results information submission requirements under Demographic and baseline characteristics in proposed § 11.48(a)(2)(iii) included the reporting of "age, gender, and any other measure(s) that were assessed at baseline . . ." and the final rule further requires the submission of baseline measure information by race and ethnicity, if collected during the clinical trial. *ClinicalTrials.gov* also provides pre-formatted categories that enable responsible parties to submit common demographic characteristics, including age, sex/gender, race, ethnicity, and region of enrollment (if assessed at baseline), to facilitate comparison across study records. Another commenter suggested requiring the listing of the targeted and actual numbers of subjects enrolled in each trial. Two specific required registration data elements proposed in the NPRM, and combined in the final rule, address this comment. The Enrollment data element specified in proposed § 11.28(a)(1)(xx) is defined in proposed § 11.10(b)(18) as "the estimated total number of human subjects to be enrolled or target number of human subjects in the clinical trial," and the Actual Enrollment data element specified in proposed § 11.28(a)(2)(vii) is defined as "for a clinical trial for which recruitment of human subjects has terminated or completed, the actual number of human subjects enrolled in the clinical trial" in proposed § 11.10(b)(27). After consideration of these comments, we maintain the proposed name of the Enrollment data element in the final rule, but we combine it with the proposed Actual Enrollment data element for convenience and consistency with the format on *ClinicalTrials.gov* prior to this rule. We clarify that with the approach in the final rule, the estimated number of human subjects to be enrolled will be retained, to allow for later display of both the estimated and actual total number of human subjects enrolled in the clinical trial. We have therefore changed the definition of Enrollment to "the estimated total number of human subjects to be enrolled (target number) or the actual total number of human subjects that are enrolled in the clinical trial. Once the trial has reached the primary completion date, the responsible party must update the Enrollment data element to reflect the actual number of human subjects enrolled in the clinical trial.'' We expect that the estimated or target enrollment for a clinical trial may change before or during the clinical trial (*e.g.,* as recruitment continues). Consistent with section 402(j)(4)(C) of the PHS Act and § 11.64(a)(1), a responsible party would be required to update the Enrollment data element not less than once every 12 months, if the anticipated or target enrollment for the clinical trial changes. This update would be in addition to the requirement in § 11.64(a), described in Section IV.D.3, that a responsible party submit the actual enrollment when the clinical trial has reached its primary completion date, *i.e.,* when the Primary Completion Date of the trial is changed to ''actual.'' This requirement is intended to provide users of *ClinicalTrials.gov* with additional information on the total number of participants enrolled in the clinical trial, which may differ from the target enrollment. (See § 11.64(a) and the discussion of Primary Completion Date'' for a discussion of this requirement.) We also note that ''enrolled,'' as defined in § 11.10(a) of the final rule, means ''a human subject's, or their legally authorized representative's, agreement to participate in a clinical trial following completion of the informed consent process, as required in 21 CFR part 50 and/or 45 CFR part 46, as applicable. For the purposes of this part, potential subjects who are screened for the purpose of determining eligibility for a trial, but do not participate in the trial, are not considered enrolled, unless otherwise specified by the protocol.'' In addition, we note that in response to comments on the update requirements in § 11.64, the Enrollment data element must be updated at the time the Primary Completion Date data element is updated to ''actual'' instead of at the time after enrollment closes.

(W) *Primary Outcome Measures and (X) Secondary Outcome Measures* are data elements expressly required by section 402(j)(2)(A)(ii)(I)(ll) of the PHS Act to be submitted as part of clinical trial information at the time of registration. Definitions of the terms ''outcome measure'', ''primary outcome measure'', and ''secondary outcome measure'' are provided and elaborated on in the preamble and subpart A of the final rule. However, section 402(j) of the PHS Act does not specify what specific information about primary and secondary outcome measures must be submitted to *ClinicalTrials.gov* at the time of registration. Under proposed § 11.28(a)(1)(xxi) and (xxii) of the NPRM, responsible parties would be required to submit the information specified in proposed § 11.10(b)(19) and (20) for each primary or secondary outcome measure in their clinical trials, namely the following: (1) The name of the specific outcome measure (*e.g.,* systolic blood pressure), (2) a description of the metric used to characterize the specific outcome measure (*e.g.,* mean value of systolic blood pressure), and (3) the time point(s) at which the measurement is assessed for the specific metric used (*e.g.,* 24 weeks after initiation of treatment). We noted in the NPRM that these requirements are consistent with the WHO Trial Registration Data Set (version 1.2.1), which specifies that each outcome include the name of the outcome, the metric or method of measurement used, and the time point(s) of primary interest. Furthermore, based on our experience in operating *ClinicalTrials.gov,* we expressed our belief that these three elements are key attributes of an outcome measure. Not only may certain outcome measures be assessed in different ways (*e.g.,* systolic blood pressure can be measured as a mean value at a specific time point or as a change from baseline), but also a single clinical trial may assess a single attribute at multiple points in time (*e.g.,* systolic blood pressure may be measured 3 months, 6 months, and 12 months after beginning treatment). Each of these would be considered a different outcome measure. We noted that ensuring that the primary and secondary outcome measures include descriptions of the measures and the time points of assessment is therefore necessary for differentiating between similar measures and for subsequently ensuring that results information is provided for all of them and in a manner that is consistent with the way in which they were pre-specified in the registry. This approach would also ensure that any changes in the outcome measure are recorded as updates to the registration information, consistent with the purpose of the data bank ''to track subsequent progress of clinical trials,'' section 402(j)(2)(A)(i) of the PHS Act (79 FR 69620).

One commenter cited findings of that commenter's research [Ref. 14] and recommended that the final rule require responsible parties to submit information on whether each outcome measure is defined in terms of a noninferiority, superiority, or equivalence hypothesis and associated information about the noninferiority or equivalence margin with relevant calculations and justification of margin selection as free-text descriptions in a new sub-element associated with each reported outcome measure. While we agree with the commenter on the potential value of this information, we note that the information should be available with the reporting of outcomes with results information under § 11.48. We do not believe that the benefits of reporting this information at registration outweighs the burden on responsible parties for reporting these details at that time. We will continue, however, to evaluate ways to accommodate this and other information related to the SAP as optional structured data elements in *ClinicalTrials.gov.* Responsible parties are able to submit this information voluntarily during registration as part of the Detailed Description data element. We also note that, during results reporting for any statistical analysis that is considered scientifically appropriate, the following information is required to be submitted: ''for a non-inferiority or equivalence test, a description of the analysis that includes, at minimum, the power calculation and non-inferiority or equivalence margin'' (see § 11.48(a)(3)(v)). After considering this comment, we maintain the proposed definition in the final rule.

(ii) Recruitment Information

(A) *Eligibility Criteria.* In § 11.10(b)(21) of the NPRM, Eligibility Criteria was described as ''a limited list of criteria for selection of human subjects to participate in the clinical trial, provided in terms of inclusion and exclusion criteria and suitable for assisting potential human subjects in identifying clinical trials of interest.'' Section 402(j)(2)(A)(ii)(II)(aa) of the PHS Act expressly requires ''eligibility criteria'' to be submitted for registration on *ClinicalTrials.gov,* but it does not define the term. In the NPRM we expressed our belief that the purpose of this data element is to enable users of the data bank to determine key characteristics of potential participants in the clinical trial and assist prospective participants in identifying clinical trials that may be of interest. Consistent with the stated objective of section 402(j)(2)(A)(i) of the PHS Act to ''enhance patient enrollment,'' we interpreted the requirement to include an ''Eligibility Criteria'' data element as part of clinical trial registration information to refer to information that can be of practical use to prospective participants who wish to determine if they potentially qualify to participate in a clinical trial and who may be interested in seeking additional information about a clinical trial. We noted that our proposed definition of "eligibility criteria" was consistent with "key inclusion and exclusion criteria" of the WHO Trial Registration Data Set (version 1.2.1) (WHO data item #14) and ICMJE registration policies [Ref. 2, 73] (79 FR 69621). A few commenters addressed the proposed Eligibility Criteria data element. One commenter agreed with the proposal that only "a limited list of criteria" be provided but suggested the need for a disclaimer on the posted record that the data element is not intended to represent all eligibility criteria. Although we do not believe that a disclaimer about the eligibility criteria data element on the record is necessary, particularly because there may be cases in which the criteria listed do represent the complete list, we will consider displaying on the public record an explanation that the listed eligibility criteria represent "key" or "selected" criteria to minimize the potential for confusion. Another commenter suggested requiring the use of standardized terminology for describing the eligibility criteria to facilitate automated, machine-based screening and matching with potential participants. While this is an active area of ongoing research, we are not aware of any widely-accepted data standards for representing eligibility criteria and the commenter did not reference any. Therefore, the final rule does not require the submission of eligibility criteria using any particular standardized terminology, although we encourage responsible parties to submit such information in as structured and standardized a fashion as possible to facilitate data reuse. After considering these comments, we maintain the proposed definition in the final rule. For submission of eligibility criteria information, responsible parties must provide a list of inclusion and exclusion criteria (*e.g.,* Inclusion Criteria: Clinical diagnosis of Alzheimer's Disease, must be able to swallow tablets; Exclusion Criteria: Insulin dependent diabetes, thyroid disease). We note that clinical trial protocols typically contain lengthy, detailed descriptions of inclusion and exclusion requirements for participants, including, for example, specific laboratory test result values. The requirements are often complex and must be assessed by a clinician or researcher involved in the clinical trial. We believe that the submission of all eligibility criteria would be burdensome for responsible parties and, instead of helping prospective participants, would prove confusing or overwhelming to them. We believe that prospective participants are better served by a more limited list of inclusion and exclusion criteria in the data bank to assist in identifying clinical trials of possible interest. Prospective participants who believe they meet the criteria listed in the data bank could discuss the clinical trial with their physician or other healthcare advisor and contact the facility-specific contact or central contact for the clinical trial for more information and a more complete assessment of eligibility. We note that for users of the data bank who want more detailed information about eligibility criteria for the purposes of interpreting clinical trial results information and better understanding the population of human subjects studied, the final rule requires responsible parties to submit protocols as part of the clinical trial results information (see Section III.D. of this preamble).

(B) *Sex/Gender.* In § 11.10(b)(22) of the NPRM, we defined the term "gender" to mean, "the biological sex of the human subjects who may participate in the clinical trial." Section 402(j)(2)(A)(ii)(II)(bb) of the PHS Act expressly requires "gender" to be submitted as clinical trial information at the time of registration, but it does not define this term. We also proposed that responsible parties would select from the following limited set of choices: "male," "female," or "both." Although no "other" option was proposed, the NPRM explained that responsible parties would be able to provide additional, optional free-text information about the gender of participants who may participate in the clinical trial (79 FR 69621).

Several commenters addressed this data element. A few requested that the final rule change the term to "sex." Others stated that use of the term "sex" would be consistent with FDA's guidance, "Evaluation of Sex-Specific Data in Medical Device Clinical Studies," in which "sex" refers to classification by reproductive organ, and "gender" refers to a person's self-representation as male or female [Ref. 95]. They also noted that FDA's guidance is based on an IOM report, "Exploring the Biological Contributions to Human Health: Does Sex Matter?" [Ref. 96].

We agree with the commenters that the proposed definition of "gender" does not align with the cited definitions and usage of the distinct terms "gender" and "sex." The commenters further suggested that we change the data element name from "Gender" to "Sex" to better align with the proposed definition. Although not mentioned specifically by commenters, we also note that the WHO Trial Registration Data Set (version 1.2.1) describes inclusion and exclusion criteria for participant selection, including age and "sex."

To further consider how the terms "gender" and "sex" are used to define recruitment/eligibility criteria in protocols, we evaluated a convenience sample of 80 study protocols made available online with publication in the Journal of the American Medical Association and the New England Journal of Medicine. Our observations suggest that although protocols use the terms "gender" and/or "sex," it was generally not possible to determine whether the usage was appropriate, as definitions of those terms were not typically included. Among the protocols examined, 23 (29 percent) used the term "gender" only, 11 (14 percent) used "sex" only, 32 (40 percent) appeared to use the terms "gender" and "sex" interchangeably, and 14 (17 percent) did not use either term. We believe it is important for the information on *ClinicalTrials.gov* to accurately represent the individuals who may participate in the clinical trial, based on information specified in the trial protocol. Based on our evaluation of this sample of protocols and the comments received on the NPRM, we have concluded that the data element needs to be sufficiently flexible to allow responsible parties to submit information about both sex and gender, if those terms are applicable to the trial being registered. We have therefore modified the proposed name of the data element to "Sex/Gender" in § 11.28(a)(2)(ii)(B) of the final rule to accommodate studies that base eligibility on sex (meaning, for purposes of this part, a person's classification as male or female based on biological distinctions) and gender (meaning, for purposes of this part, a person's self-representation of gender identity). Similarly, to reflect both terms, we have updated the definition of "Sex/Gender" to be "the sex and, if applicable, gender of the human subjects who may participate in the clinical trial" in § 11.10(b)(22). The responsible party must indicate the sex of the individuals who may participate in the clinical trial using the following options available on *ClinicalTrials.gov* for this data element: "male," which indicates that only male participants are being studied, "female," which indicates that only female participants are being studied, and "all" which indicates that the recruitment criteria do not limit eligibility based on the sex of participants. In addition, if eligibility for the clinical trial is based on gender, the responsible party may also select from the following options to provide details about gender: ''yes'' (meaning eligibility is based on gender) or ''no'' (meaning eligibility is not based on gender). If the responsible party selects ''yes,'' descriptive information about gender criteria may be provided in the optional, additional, free-text element. Information on gender is required to be submitted only if gender is used as an eligibility/recruitment criterion for the clinical trial. We further note that we consider the Sex/Gender data element complementary to the limited list of criteria submitted as part of the Eligibility Criteria data element, but provision of information on sex/gender in that data element does not substitute for the requirement to provide the Sex/Gender data element.

(C) *Age Limits.* In § 11.10(b)(23) of the NPRM, we defined this term to mean, ''the minimum and maximum age of human subjects who may participate in the clinical trial, provided in relevant units of time.'' Section 402(j)(2)(A)(ii)(II)(cc) of the PHS Act expressly requires ''age limits'' to be submitted as clinical trial information at the time of registration, but it does not define the term (79 FR 69621). We received no comments and therefore retain the proposed data element and definition in the final rule. We clarify, however, that the responsible party selects the unit of time from the following limited set of choices: ''years,'' ''months,'' ''weeks,'' ''days,'' ''hours,'' ''minutes,'' and ''N/A'' (*i.e.,* no limit). These structured choices are consistent with current practice on *ClinicalTrials.gov* and facilitates more specific searches by age limits (*e.g.,* finding studies recruiting children aged 24 to 36 months versus adults aged 24 to 36 years).

(D) *Accepts Healthy Volunteers.* In § 11.10(b)(24) of the NPRM, we defined the Accepts Healthy Volunteers data element to mean ''whether human subjects who do not have a disease or condition, or related conditions or symptoms, under study in the clinical trial are permitted to participate in the clinical trial.'' Section 402(j)(2)(A)(ii)(II)(dd) of the PHS Act requires the submission of information about ''whether the trial accepts healthy volunteers.'' (79 FR 69621) We received no comments and therefore retain the proposed data element and definition in the final rule, except we delete the word ''whether'' in the definition for additional clarity. We note that we consider any human participant in a clinical trial to be a human subject regardless of whether he or she is a healthy volunteer.

(E) *Overall Recruitment Status.* Under § 11.10(b)(25) of the NPRM, we defined the Overall Recruitment Status data element as ''the recruitment status for the clinical trial as a whole, based upon the status of the individual sites. If at least one facility in a multi-site clinical trial has an individual site status of 'recruiting,' then the overall recruitment status for the trial must be 'recruiting.' '' Section 402(j)(2)(A)(ii)(II)(ee) of the PHS Act requires ''overall recruitment status'' to be submitted as clinical trial information at the time of registration, but it does not define the term. To facilitate searching for clinical trials by recruitment status and to allow information to be compared across clinical trials, we also stated in the NPRM that responsible parties would be required to select from the following limited set of choices: ''Not yet recruiting'' (participants are not yet being recruited); ''Recruiting'' (participants are currently being recruited, whether or not any participants have yet been enrolled); ''Enrolling by invitation'' (participants are being, or will be selected from a predetermined population); ''Active, not recruiting'' (study is ongoing, meaning participants are being treated or examined, but new participants are not currently being recruited or enrolled); ''Completed'' (the study has concluded normally; participants are no longer being examined or treated, *i.e.,* last patient's last visit has occurred); ''Suspended'' (recruiting or enrolling participants has halted prematurely but potentially will resume), ''Terminated'' (recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated), and ''Withdrawn'' (study halted prematurely, prior to enrollment of first participant). No ''other'' option was proposed. We invited public comment on whether the proposed options are sufficient to accurately describe the overall recruitment status of clinical trials subject to the proposed rule. We also noted that the proposed definition of ''overall recruitment status'' is consistent with ''recruitment status'' in the WHO Trial Registration Data Set (version 1.2.1) (WHO data item #18) and ICMJE registration policies [Ref. 2, 73] (79 FR 69621).

We received no comments and therefore retain the proposed definition in the final rule. The final rule requires responsible parties to provide and update information for the Overall Recruitment Status data element. Such a requirement will provide users of *ClinicalTrials.gov* with an effective means of tracking the progress of clinical trials, as required by section 402(j)(2)(A)(i) of the PHS Act. However, we clarify the descriptions for the following four choices identified in the NPRM for the Overall Recruitment Status data element: ''Active, not recruiting'' indicates that a ''study is continuing, meaning that participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled;'' ''Completed'' indicates that ''the study has concluded normally; participants are no longer receiving an intervention or being examined, *i.e.,* the last patient's last visit has occurred;'' ''Suspended'' indicates that a ''study halted prematurely but potentially will resume;'' and ''Terminated'' indicates that a ''study halted prematurely and will not resume; participants are no longer being examined or receiving an intervention.'' These descriptions are clearer and more accurate for the data element choices. We remove the term ''treated'' from the description of these options and instead use the phrase ''receiving an intervention'' for greater accuracy because not all clinical trials are conducted to evaluate whether interventions are efficacious for the treatment of the disease or condition that is the focus of the study. We note that ''receiving an intervention'' includes receiving a placebo or receiving no intervention, as assigned in the study protocol. The other modifications clarify that the status relates to the entire study, not just the aspect of the study that involves recruitment. We also note that if a clinical trial is registered before it is open to recruitment, we would expect the Overall Recruitment Status to be ''Not yet recruiting.'' When the clinical trial opens for enrollment, we would expect the Overall Recruitment Status to be ''Enrolling by invitation'' if human subjects are selected from a predetermined population or ''Recruiting'' if the study is open to volunteers who meet the study's eligibility criteria. As indicated in the discussion of the Study Start Date data element, for this rule, if a clinical trial is registered prior to enrollment of the first subject and the clinical trial is subsequently halted before the first subject is enrolled, we would expect the responsible party to update the Overall Recruitment Status data element to ''Withdrawn.''

We believe that updating the Overall Recruitment Status data element will provide users of *ClinicalTrials.gov* with an effective means of tracking the progress of clinical trials, as the data bank is intended to do (see section 402(j)(2)(A)(i) of the PHS Act). In the case of a clinical trial that is halted before the first subject is enrolled (*i.e.,* a status of Withdrawn), this information will explain why no results information can be expected or is required to be submitted. In the case of a clinical trial for which recruitment is prematurely halted (*i.e.,* a status of Suspended or Terminated), this information will allow potential human subjects to determine whether enrollment is likely to resume. Such information will also assist in the interpretation of results information, for example, by providing an explanation of why some clinical trial outcomes were not achieved and/or enrollment was significantly below the target. We note that when a study has reached its study completion date, as defined in § 11.10(a), the Overall Recruitment Status would be Completed, unless the responsible party terminates the study, which would be reflected in a status of Terminated.

(F) *Why Study Stopped.* Proposed § 11.10(b)(26) of the NPRM defined the Why Study Stopped? data element to mean "for a clinical trial that is suspended or terminated or withdrawn prior to its completion as anticipated by the protocol, a brief explanation of the reason(s) why such clinical trial was stopped." We proposed allowing responsible parties to enter this information as a free-text response, to provide them with the flexibility to explain the reason(s) why a clinical trial stopped prematurely. While this information is not required for submission by section 402(j) of the PHS Act, we indicated that it is important to communicate to users of the data bank why a clinical trial was suspended, terminated, or withdrawn (*e.g.,* safety concerns, difficulties in recruitment, financial reasons). Such information also furthers the statutory objective stated in section 402(j)(2)(A)(i) of the PHS Act to enable users "to track subsequent progress of clinical trials." As we stated in the NPRM, for these reasons requiring this information improves and does not reduce the clinical trial information available in the data bank, consistent with the authority granted to the Agency under section 402(j)(2)(A)(iii) of the PHS Act. We also indicated our concern that if such information were not required in each instance in which a clinical trial is stopped prematurely (*i.e.,* not according to the protocol), it might be submitted only for some trials, resulting in inconsistencies in the information available for registered clinical trials (79 FR 69622).

Two commenters requested that for this data element the final rule require only the submission of reasons for stopping a study that are directly related to safety. These commenters asserted that any other reasons would be business reasons, which would be confidential commercial information prohibited from disclosure. As we explained in the NPRM, we believe it is important for responsible parties to provide any reasons for stopping a study, whether or not they relate to safety. This increased transparency will assist the public, including patients, in understanding the reasons why a trial was stopped. We also note that this proposed definition specifies that any explanation provided be brief; therefore, we do not believe that a responsible party will need to provide any confidential commercial or proprietary information when submitting the information for this data element. However, even if the summary results information required to be submitted and posted does include such proprietary information, as discussed above, section 402(j) of the PHS Act and this final rule constitute authorization by law to disclose the information.

After considering the comments, we are maintaining the NPRM definition in the final rule. We note that §§ 11.10(b)(26) and 11.64(a)(1) specify that a brief explanation for why the clinical trial was stopped must be submitted if the Overall Recruitment Status is "Suspended," "Terminated," or "Withdrawn." In most cases, the Overall Recruitment Status of a clinical trial would be other than Suspended, Terminated, or Withdrawn at the time of registration (*e.g.,* a status of "Not yet recruiting" or "Recruiting"). The responsible party would not be required to complete the Why Study Stopped data element unless and until there is a change in the Overall Recruitment Status to Suspended, Terminated, or Withdrawn. (The Why Study Stopped data element would not be available to a responsible party during the registration process nor to the public in the posted clinical trial record, unless and until the Overall Recruitment Status indicates that the clinical trial is Suspended, Terminated, or Withdrawn.) However, if a clinical trial is suspended, terminated, or withdrawn, the responsible party would be required to update the Overall Recruitment Status data element and, consistent with § 11.64(a)(1), submit the Why Study Stopped data element not later than 30 calendar days after the date of the suspension, termination, or withdrawal of the clinical trial to explain why the study stopped.

(G) *Individual Site Status.* In proposed § 11.10(b)(28) of the NPRM, we defined this data element as "the recruitment status of each participating facility in a clinical trial." Section 402(j)(2)(A)(ii)(II)(ff) of the PHS Act expressly requires "individual site status" to be submitted as a clinical trial information at the time of registration, but it does not define the term. To be consistent with the proposed Overall Recruitment Status data element, we also stated in the NPRM that responsible parties would be required to indicate the individual site status by selecting from the following limited set of choices: "Not yet recruiting," "Recruiting," "Enrolling by invitation," "Active, not recruiting," "Completed," "Suspended," "Terminated," and "Withdrawn." No "other" option was proposed. We invited public comment on whether the proposed options were sufficient to accurately describe the individual site status of clinical trials that would be subject to the proposed rule (79 FR 69623). Two commenters suggested that the final rule remove the proposed requirement for registering and updating the Individual Site Status data element for each participating facility in the trial. The Individual Site Status data element is required by section 402(j)(2)(A)(ii)(II)(ff) of the PHS Act. Furthermore, such information supports the purpose of *ClinicalTrials.gov* to enhance patient enrollment by assisting potential human subjects who search for clinical trials by location and wish to retrieve information about only those trials that are open to recruitment in specified locations. We clarify that when the Overall Recruitment Status is a status other than Recruiting, the Individual Site Status data element no longer needs to be updated because the Overall Recruitment Status would apply to each individual site. We also note that the update burden for responsible parties is reduced by tools available in the PRS that allow the Individual Site Status data element to be easily changed (*e.g.,* from Recruiting to Active, not recruiting) for many sites at once. After considering the comments, we retain the proposed definition in the final rule. However, we clarify these descriptions as described for the Overall Recruitment Status data element. Specifically, we modify the following four choices for the Individual Site Status data element from the limited set described in the NPRM: "Active, not recruiting" indicates that a study is continuing, meaning that participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled; "Completed" indicates that the study has concluded normally and that participants are no longer receiving an intervention or being examined, *i.e.,* the last patient's last visit has occurred; "Suspended" indicates that a study halted prematurely but potentially will resume; and "Terminated" indicates that a study halted prematurely and will not resume and that participants are no longer being examined or receiving an intervention. We note that when a study has reached its study completion date, as defined in § 11.10(a), the Individual Site Status would be Completed, unless the responsible party terminates the study, which would be reflected as a status of Terminated.

(H) *Availability of Expanded Access.* Section 402(j)(2)(A)(ii)(II)(gg) of the PHS Act specifies that if a drug (including a biological product) being studied in an applicable clinical trial is not approved under section 505 of the FD&C Act or licensed under section 351 of the PHS Act, the responsible party must specify (1) "whether or not there is expanded access to the drug under section 561 of the [FD&C Act] for those who do not qualify for enrollment in the clinical trial" and, if so, (2) "how to obtain information about such access." As we expressed in the NPRM, we believe the purpose of this requirement is to allow prospective human subjects and other users of the data bank to readily identify unapproved drugs that are available through expanded access under section 561 of the FD&C Act and to direct these users to additional information about the expanded access. Therefore, we proposed that responsible parties meet the requirements of section 402(j)(2)(A)(ii)(II)(gg) of the PHS Act by indicating in the clinical trial record whether expanded access is available for the drug under study (*i.e.,* either "yes" or "no") and, if yes, submitting the additional information about the expanded access in the form of an expanded access record under proposed § 11.28(c) and including the NCT number for the expanded access record in the record of a clinical trial that studies the drug.

In the NPRM, we proposed to require the submission of information to create an expanded access record using the statutory authority at section 402(j)(2)(A)(iii) of the PHS Act, which allows the Secretary by regulation to modify the requirements for clinical trial registration information if the Secretary provides a rationale for why such a modification "improves and does not reduce such clinical trial information." Information about the availability of expanded access would be a data element that a responsible party is required to submit under section 402(j)(2)(A)(ii)(II) of the PHS Act and, therefore, would meet the definition of "clinical trial information" in section 402(j)(1)(A)(iv) of the PHS Act. We indicated that the additional data elements describing expanded access availability would improve, and not reduce, this clinical trial information by providing users with more complete and consistent information about expanded access programs for drugs studied in applicable clinical trials than would be available pursuant to section 402(j)(A)(ii)(II)(gg) of the PHS Act alone. We further concluded that we have the authority to require that the clinical trial information required under proposed § 11.28(c) be submitted by creating a separate expanded access record in *ClinicalTrials.gov* under section 402(j)(2)(B)(iv) of the PHS Act, as the expanded access record would ensure that the public may more easily use the data bank to determine whether there is expanded access to a drug and compare different expanded access programs.

The approach we proposed is similar to the one used to submit a description of whether, and through what procedure, the manufacturer or sponsor will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded access use of the investigational drug, particularly in children, prior to the enactment of FDAAA [Ref. 78, 79]. Proposed § 11.28(a)(2)(ix) would require the responsible party for an applicable clinical trial of a drug that is not approved under section 505 of the FD&C Act to submit the Availability of Expanded Access data element, which was defined in proposed § 11.10(b)(29) to include "[a]n indication of whether there is expanded access to the drug under section 561 of the [FD&C Act] (21 U.S.C. 360bbb) for those who do not qualify for enrollment in the applicable clinical trial," and, if expanded access is available, "the NCT number of the expanded access record." The availability of expanded access would be indicated by a yes/no designation in *ClinicalTrials.gov.* In addition, if the drug studied in the clinical trial is available through expanded access under section 561 of the FD&C Act and an expanded access record has not been created, under the NPRM the responsible party would be required to create an expanded access record consisting of the information specified in proposed § 11.28(c). The posted expanded access record would be assigned its own NCT number and thus would be searchable and retrievable independent of the record(s) for the applicable clinical trial(s) of the investigational product for which expanded access is available.

Under the proposed approach, we stated that we would expect the sponsor of the expanded access program to be responsible for (1) informing the responsible party(ies) for any applicable clinical trials that study the drug available under expanded access of the creation of an expanded access record and (2) providing them with the NCT number for the expanded access record. The responsible party(ies) would be required to update the related clinical trial record under proposed § 11.64(b) to include the NCT number for the expanded access record within 30 calendar days of receipt. Accordingly, a single expanded access record could be linked, via the expanded access record NCT number, to several applicable clinical trials that study the drug that is available via expanded access. If an expanded access record has already been completed at the time of registration of an applicable clinical trial (*e.g.,* to fulfill the registration or updating requirements for a previously registered applicable clinical trial), the responsible party would be required to submit the NCT number for that expanded access record as part of the Availability of Expanded Access data element. The NPRM also noted that expanded access is available via treatment INDs, which provide widespread access; expanded access for intermediate-size patient populations; and expanded access for individual patients (79 FR 69624). As we stated in the NPRM, because requests for individual patient access are generally handled on a case-by-case basis, a responsible party likely would not be able to provide detailed information describing individual patient access at the time of registering an applicable clinical trial. For cases in which expanded access is only available for individual patients on a case-by-case basis, we stated that we would not require the responsible party to submit the elements of the expanded access record, as described below, and we would expect that users of *ClinicalTrials.gov* would direct inquiries regarding individual patient access to the facility contact.

Commenters addressed issues related to the Availability of Expanded Access data element in proposed § 11.28(a)(2)(ix) and its definition in proposed § 11.10(b)(29). A few commenters expressed support for the proposed data element and its definition. A few commenters supported, in particular, the proposed requirement that responsible parties for applicable clinical trials of drugs available through expanded access provide the NCT number for the expanded access record to permit linking from clinical trial records to additional information about the expanded access program. One commenter opposed the proposed requirement for creating expanded access records because of concerns that such records may (1) mislead patients into believing that no other opportunities to obtain expanded access exist beyond what is described in expanded access records because the proposal does not require the submission of information about individual patient access and/or (2) confuse patients regarding the distinction between clinical trials and expanded access programs. We agree with the commenter that requiring the submission of registration information for only certain types of available expanded access programs, as proposed, could be problematic. In addition, section 402(j)(2)(A)(ii)(II)(gg) of the PHS Act broadly requires "specify[ing] whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act" and does not explicitly exclude individual patient expanded access.

After considering these comments and the statutory provision, in the final rule we have revised the requirements regarding the information to be submitted about the availability of expanded access to investigational drug products (including biological products). We have also clarified that "drug" means "drug product." Therefore, under the final rule, if an investigational drug product (including a biological product) is available for any type of expanded access, and the responsible party for an applicable clinical trial of that product is both the manufacturer of the product and the sponsor of the applicable clinical trial, the responsible party must create an expanded access record for the investigational product by submitting the expanded access data elements specified in § 11.28(c) of the final rule. We note that only one expanded access record should be created for any given investigational product, even if the investigational product is being made available for individual patient expanded access (*i.e.*, the responsible party should not create an expanded access record for each instance of individual patient access). This approach permits users of *ClinicalTrials.gov* to identify the full range of expanded access availability under section 561 of the FD&C Act by searching posted expanded access records.

Another commenter requested that posted clinical trial records be made "separate and distinct" from expanded access records to avoid confusion and suggested that *ClinicalTrials.gov* provide sponsors with the ability to link to their expanded access policy and contact Web pages. We recognize the potential for confusion between expanded access records and clinical trial records and have sought to help users distinguish between them (*e.g.*, prominently displaying Study Type of "Expanded Access" versus "Interventional Study," and Overall Recruitment Status displayed as "Expanded access is currently available for this treatment" versus "This study is currently recruiting participants"). We will continue to explore ways to differentiate between the two types of records. With regard to the second comment, we note that *ClinicalTrials.gov* currently permits responsible parties to submit URLs of Web sites through the optional Links data element.

One commenter requested that the final rule define "expanded access program" and clarify for which expanded access programs the data elements specified in proposed § 11.28(c) would be required under the final rule. In particular, although the preamble of the NPRM stated that responsible parties would not be required to create expanded access records when expanded access is available only through individual patient access, this distinction was not specified in the codified section of the NPRM. The commenter suggested that the final rule state explicitly which types of expanded access programs require the creation of expanded access records, such as by adding a definition of expanded access in § 11.10 of the final rule. Another commenter suggested that the final rule narrow the proposed definition of Availability of Expanded Access to section 561(c) of the FD&C Act, thereby limiting the types of expanded access programs "to intermediate-size and large-size treatment INDs with established inclusion/exclusion enrollment parameters and exclude[ing] emergency situations and individual patient access to INDs intended for serious diseases."

We agree that the codified section of the proposed rule did not provide specificity with respect to the term "expanded access program." After considering the issue, in the final rule, we have revised the phrase "expanded access program" to "expanded access" for an expanded access record to more accurately characterize the mechanism through which a responsible party makes its investigational product available under expanded access. This flexibility will accommodate both situations in which a responsible party has established what it considers to be an expanded access program and those in which a responsible party makes its investigational product available through expanded access but does not itself characterize that availability as a "program." Furthermore, because the statutory requirement for providing information about expanded access did not explicitly exclude individual patient expanded access, we disagree with the commenter that *ClinicalTrials.gov* should only include information on certain types of expanded access. The final rule broadens the scope of the proposed rule to include and define all three types of expanded access under section 561 of the FD&C Act: (1) For individual patients, including emergency use, as specified in 21 CFR 312.310; (2) for intermediate-size patient populations as specified in 21 CFR 312.315; and (3) under a treatment IND or treatment protocol as specified in 21 CFR 312.320. Section 11.10(b)(28) of the final rule, which defines the Availability of Expanded Access data element, clarifies that if the investigational product is available for any of these three types of expanded access, the NCT number of a corresponding expanded access record must be submitted. As such, the definition of and requirements for the Availability of Expanded Access data element in the final rule cover all types of expanded access for investigational drug products (including biological products) under section 561 of the FD&C Act, consistent with the statutory requirements. Additionally, § 11.28(c) of the final rule, which indicates the data elements that must be submitted for an expanded access record, lists the Expanded Access Type data element, which is defined as "[t]he type(s) of expanded access for which the investigational drug product is available, as specified in § 11.10(b)(28)."

A few commenters expressed concern that requiring responsible parties who are not industry sponsors and manufacturers of the drug to create expanded access records could be problematic because only a manufacturer would know when expanded access to a drug becomes available and would possess the information required to be submitted under § 11.28(c) and updated under § 11.64. Accordingly, they suggested that the final rule only require responsible parties who are industry sponsors of relevant trials and manufacturers of the drug to create expanded access records for their drugs. Several commenters suggested that the final rule require drug manufacturers to notify responsible parties for applicable clinical trials when drugs become available through expanded access programs and that *ClinicalTrials.gov* could notify responsible parties who are not drug manufacturers when an expanded access record has been submitted for the drug being studied in their applicable clinical trials. They also requested guidance on whether the Agency would recommend that "investigators of investigator-initiated trials" seek agreements from manufacturers that require notification that an expanded access program for a studied drug becomes available. One other commenter requested clarification on two issues: (1) How independent investigators who are responsible parties for applicable clinical trials would know when and what information to submit for an expanded access record when the manufacturer makes a drug they are studying available through expanded access and (2) whether the proposed rule intended for the manufacturer to provide one expanded access record per drug and an indication for the purposes of the registration requirements.

We agree with the concerns raised by these commenters and have modified the final rule to specify that the requirement to submit information for the Availability of Expanded Access data element only applies to a responsible party who is both the manufacturer of the investigational drug product (including a biological product) and the sponsor of the applicable clinical trial for that investigational product. We believe that these new requirements will decrease the burden on responsible parties who are not the manufacturer without impeding access to information posted on *ClinicalTrials.gov* about the availability of investigational drug products (including biological products) for expanded access. At the same time, these new requirements will ensure that only one expanded access record is created for each investigational drug product that is available for expanded access for any disease or condition. We wish to emphasize, however, that an expanded access record is required to be submitted regardless of whether the responsible party registering the applicable clinical trial, who is both the sponsor of the applicable clinical trial and the manufacturer of the investigational product, itself oversees the availability of the investigational product for expanded access (*i.e.,* it is required even in situations where the expanded access availability is managed by a different entity). If certain data elements required for submitting an expanded access record under § 11.28(c) are unknown to the responsible party because the expanded access availability is managed by a different entity, the responsible party will need to consult with NIH concerning these data elements before submitting the expanded access record. Instructions for contacting NIH will be available at *https://prsinfo.clinicaltrials.gov* (or successor site).

In addition, responsible parties will no longer need to be notified by the manufacturer when an investigational drug product (including a biological product) is available through expanded access. We note that there may be cases in which the sponsor who is the manufacturer of the unapproved drug product (including a biological product) may designate the principal investigator to be the responsible party of an applicable clinical trial of that product. Based on our experience operating *ClinicalTrials.gov,* we expect the designation of a principal investigator to be the responsible party by a manufacturer to be a rare event. If it does occur, we recommend that the sponsor provide the necessary information to the responsible party or, on an optional basis, create an expanded access record to allow information about expanded access to be shared with individuals who do not qualify for enrollment in the clinical trial.

One commenter suggested that *ClinicalTrials.gov* provide links between applicable drug clinical trial records and expanded access records for the studied drugs and provide appropriate caveats about the expanded access programs. *ClinicalTrials.gov* is able to provide the appropriate links between matched clinical trial records and expanded access records after a responsible party has identified in the clinical trial record(s) that the investigational drug product (including a biological product) is available through a particular expanded access program. Once the responsible party submits the NCT number for the relevant expanded access record, *ClinicalTrials.gov* creates and displays a link on the clinical trial record to the related record for the expanded access program. We can also provide links from expanded access records to the matched clinical trial records. We note that *ClinicalTrials.gov* currently provides links to information about expanded access on FDA's Web site (*e.g., www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm*). As suggested by the commenter, we will consider providing additional information about expanded access or links on *ClinicalTrials.gov.*

Taking into consideration the commenters' suggestions and the statutory requirements for providing information about expanded access as part of clinical trial registration information, § 11.28(a)(2)(ii)(H) of the final rule modifies the Availability of Expanded Access data element with respect to which responsible parties must submit the data element and by expanding the submission requirement to include applicable clinical trials for which the investigational drug products (including biological products) that are being studied are available through individual patient expanded access, including for emergency use. The Availability of Expanded Access data element as defined in § 11.10(b)(28) and specified in § 11.28(a)(2)(ii)(H) of the final rule indicates whether the unapproved drug product (including a biological product) studied in the applicable clinical trial is available for expanded access under section 561 of the FD&C Act for those who do not qualify for enrollment in the applicable clinical trial (*i.e.,* "yes," "no," or "unknown"). Under the final rule, the requirement to submit the data element is limited to a responsible party for an applicable clinical trial of an unapproved drug product (including a biological product) who is both the manufacturer of the drug product and the sponsor of the trial. Therefore, a responsible party for an applicable drug clinical trial who is not the manufacturer of the drug product (including a biological product) would not be required to submit information for the Availability of Expanded Access data element (*i.e.,* response of "unknown"). This modification will decrease the burden on responsible parties who are not the manufacturer but will still help ensure the availability of information about expanded access on *ClinicalTrials.gov.*

For an investigational drug product (including a biological product) that is available through expanded access, including for individual patients, the responsible party who is both the manufacturer of the investigational drug product (including biological product) and the sponsor of an applicable clinical trial must provide the NCT number of the expanded access record as part of the clinical trial information for that applicable clinical trial. If an expanded access record for the investigational drug product (including a biological product) has not yet been submitted to *ClinicalTrials.gov,* the responsible party is required to create an expanded access record as specified in § 11.28(c). This new requirement will provide users of *ClinicalTrials.gov* with a way to obtain information about available expanded access to an investigational drug product (including a biological product) as required by the statute, including for individual patients.

We note that even though the expanded access record NCT number is a registration data element, a responsible party is not required to submit the expanded access data elements under § 11.28(c) and obtain an NCT number for that expanded access record prior to the date on which clinical trial registration information under § 11.28(a) is due for the first applicable clinical trial of that investigational product that the responsible party registers. Rather, the responsible party is required at the time it submits clinical trial registration information for the applicable clinical trial to indicate that expanded access is available, submit the applicable data elements required by § 11.28(c), and indicate that the NCT number for the expanded access record is "pending." As described previously, within 30 calendar days of receipt of the NCT number for the expanded access record, the responsible party is required to update the applicable clinical trial record with the NCT number assigned to the expanded access record. Finally, we note both that expanded access to an investigational drug product (including a biological product) may not be available at the time an applicable clinical trial is registered and that an expanded access program may be discontinued on a date other than the study completion date of an applicable clinical trial. We believe that information about changes in the availability of expanded access must be conveyed to users of *ClinicalTrials.gov* in a timely manner and therefore Availability of Expanded Access is a data element that must be updated more frequently than once every 12 months. Accordingly, as explained in further detail in § 11.64, the Availability of Expanded Access data element must be updated within 30 calendar days of expanded access becoming available, consistent with § 11.64(a).

(iii) Location and Contact Information

(A) *Name of the Sponsor.* In § 11.10(b)(30) of the NPRM, Name of the Sponsor is defined as "the name of the entity or the individual that is the sponsor of the clinical trial, as defined in § 11.10(a)." Section 402(j)(2)(A)(ii)(III)(aa) of the PHS Act expressly requires responsible parties to submit the name of the sponsor as part of clinical trial information at the time of registration. In the NPRM, the term "sponsor" is defined as "either a 'sponsor' or 'sponsor-investigator,' as each is defined in 21 CFR 50.3, or any successor regulation." As we indicated, if the sponsor is a sponsor-investigator, we would expect the name of the sponsor to be the name of an individual; otherwise the name of the sponsor may be an organizational name (79 FR 69624). We received no comments on this data element and therefore retain the proposed definition in the final rule, however, we made minor grammatical corrections (*e.g.,* changing "that" to "who").

(B) *Responsible Party, by Official Title.* Section 11.10(b)(31) of the NPRM defined Responsible Party, by Official Title to mean "(i) Indication of whether the responsible party is the sponsor of the clinical trial, as that term is defined in 21 CFR 50.3, the sponsor-investigator, as that term is defined in 21 CFR 50.3, or a principal investigator designated pursuant to this part; and (ii) Either: (A) The official name of the entity, if the responsible party is an entity; or (B) The official title and primary organizational affiliation of the individual, if the responsible party is an individual." Section 402(j)(2)(A)(ii)(III)(bb) of the PHS Act expressly requires the submission of the "responsible party, by official title" as part of clinical trial registration information. When an organizational entity is the responsible party, we noted our belief that the official name of the entity (*e.g.,* company name, university name, government agency name) must be included to satisfy the requirement for the Responsible Party, by Official Title data element. When the responsible party is an individual, we noted our belief that the official job title and the organizational affiliation of the individual are necessary (*e.g.,* "Director of Clinical Research, Institution X" or "Professor of Medicine, Institution Y"). In addition, we indicated that we believe it is necessary to ask whether the responsible party is the sponsor, sponsor-investigator, or a principal investigator designated by the sponsor, grantee, contractor, or awardee. Collection of this information will help determine what information must be provided for the official title and will allow a principal investigator to provide an affirmative acknowledgement that he or she has been designated the responsible party (79 FR 69624). We received no comments on this data element and therefore retain the proposed definition in the final rule. We note that an individual who serves as a responsible party and has multiple affiliations (*e.g.,* a research university and a teaching hospital, a research institution and a private company) would be required to submit only one such affiliation, namely, the affiliation that the individual considers their primary affiliation. A related data element, Responsible Party Contact Information, is defined in § 11.10(b)(37).

(C) *Facility Information.* In § 11.10(b)(32) of the NPRM, we defined Facility Information as (1) "Facility Name, meaning the full name of the organization where the clinical trial is being conducted"; (2) "Facility Location, including city, state, country and zip code for U.S. locations (including territories of the United States) and city and country for locations in other countries," and (3) for each participating facility either "a Facility Contact, including the name or title, telephone number, and email address of a person to whom questions concerning the trial and enrollment at that site can be addressed" or a "Central Contact Person, including the name or title, toll-free telephone number and email address of a person to whom questions concerning enrollment at any location of the trial can be addressed." Section 402(j)(2)(A)(ii)(III)(cc) of the PHS Act expressly requires the submission of "the facility name and facility contact information" as part of clinical trial information at the time of registration and describes facility contact information as "including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed." Section 402(j)(2)(B)(i) of the PHS Act requires the Director to ensure that the public may search the entries in *ClinicalTrials.gov* by one or more of several enumerated criteria, one of which is "location of the clinical trial." In the NPRM, we interpreted "location of the clinical trial" to mean each location of the clinical trial because section 402(j)(2)(A)(ii)(III)(cc) of the PHS Act describes "facility contact information" as meaning contact information "for each clinical trial location." To enable the public to search the data bank by the location of the clinical trial; in our view, satisfactory searching of the data bank by location can only be accomplished if responsible parties submit complete facility location information for each clinical trial location. Also, in our view, a toll-free telephone number is not a substitute for the location information for each facility or site but rather is a source of supplementary information about the clinical trial overall and an alternative to site-specific contact information for each location. Therefore, the Agency proposed to exercise its authority under section 402(j)(2)(A)(iii) of the PHS Act as we noted our belief that including this information improves and does not reduce the clinical trial registration information. We noted that our proposal to permit responsible parties to submit Central Contact instead of Facility Contact was intended to reduce the burden on responsible parties who must submit clinical trial registration information. However, the central contact person should be fully informed of, and able to respond to, requests for information concerning the clinical trial at all of its sites (79 FR 69625).

Commenters addressed the proposed Facility Information data element. One commenter requested that facilities located outside of the United States be excluded from the submission requirements. We disagree with this comment. As discussed in the preamble of the NPRM, we interpret "location of the clinical trial" in this context as meaning each location of the clinical trial because section 402(j)(2)(A)(ii)(III)(cc) of the PHS Act describes "facility contact information" as meaning contact information "for each clinical trial location." Because the final rule is not limited to applicable clinical trials that are conducted in the United States, and because it is important that the database be complete in order to allow users to search for registered trials by key characteristics (including where they are being conducted), the Facility Information data element must include information about all facility locations, including those outside the United States. A few commenters suggested that the final rule limit the required Facility Contact Information sub-element to information about the facility, rather than also requiring information about an individual, as proposed. One commenter suggested requiring only a toll-free telephone number for the Central Contact Person and removing the proposed requirement for a name or title and an email address to reduce the reporting burden and the submission of personally identifiable information. Another commenter suggested that providing contact information for each facility participating in a trial would increase the burden on academic sites to respond to inquiries and requested confirmation that a toll-free phone number is only required for the Central Contact Person, if provided, and not for each study facility. One commenter suggested that the final rule clarify that the proposed Central Contact Person sub-element defined in § 11.10(b)(32)(iii)(B) applies to the entire trial. Another commenter supported the inclusion of contact information for someone who is knowledgeable about the trial at each facility.

We disagree with these comments and maintain the definition of "Facility Information." As explained in the preamble of the NPRM, the requirement that the responsible party must submit to the data bank the location of each facility at which the clinical trial is conducted will allow users of *ClinicalTrials.gov* to search the data bank by each clinical trial location (79 FR 69625). We believe that providing "the name or title . . . of a person to whom questions concerning the trial and enrollment at that site can be addressed . . ." helps users identify who they can contact for additional information about a trial. In addition, we believe that a toll-free telephone number is not a substitute for the location information for each facility, but rather is a source of supplementary information about the clinical trial overall and an alternative to site-specific contact information for each location. Because a toll-free phone number in one country may not be applicable when a call originates in another country, and given the worldwide prevalence of electronic communication, we believe that submitting email addresses is necessary to provide an alternate method of contacting someone knowledgeable about the trial. Finally, we note that proposed § 11.10(b)(32)(iii)(B) already specified "a person to whom questions concerning enrollment at any location of the trial can be addressed" and we believe that this description sufficiently indicates that the person must be knowledgeable about all the locations for a trial.

For these reasons, we believe including the information required in the final rule improves and does not reduce the clinical trial registration information. Under our authority in section 402(j)(2)(A)(iii) of the PHS Act, we therefore modify in § 11.28(a)(2)(iii)(C) the requirement in section 402(j)(2)(A)(ii)(III)(cc) of the PHS Act for "facility name and facility contact information" to require Facility Information for each participating facility in the clinical trial, as defined in § 11.10(b)(31). As noted above, the Agency intends to exercise its authority under section 402(j)(2)(B)(i) of the PHS Act to enable the public to search the data bank by the location of a clinical trial; in our view, satisfactory searching by location can only be accomplished if responsible parties submit complete facility location information for each clinical trial location. In addition, the final rule allows, but does not require, responsible parties to submit the name or title of a person knowledgeable about the clinical trial at each site, along with the phone number and email address of that person, which would help prospective human subjects obtain additional, specific information about a clinical trial at a particular location. Responsible parties will also be permitted to submit a Central Contact Person instead of Facility Contact, which will reduce the burden on responsible parties who must submit clinical trial registration information. As noted in the NPRM preamble, the central contact person should be fully informed of, and able to respond to, requests for information concerning the clinical trial for all its sites (79 FR 69625).

(iv) Administrative Data

Section 402(j)(2)(A)(ii)(IV) of the PHS Act provides for certain "administrative data" to be submitted by responsible parties as part of clinical trial registration information; however, unlike the other categories of clinical trial registration information, the statute specifies that the Secretary may make administrative data "publicly available as necessary." Accordingly, in the NPRM, we indicated whether we would make the information publicly available through *ClinicalTrials.gov.*

(A) *Unique Protocol Identification Number.* In § 11.10(b)(33) of the NPRM, we defined "unique protocol identification number" to mean "any unique identification number assigned to the protocol by the sponsor." Section 402(j)(2)(A)(ii)(IV)(aa) of the PHS Act expressly requires the submission of "the unique protocol identification number" as part of clinical trial information at the time of registration, but it does not define the term (79 FR 69625). We did not receive any comments on this data element, but we are modifying the proposed data element in the final rule for accuracy. To clarify that the unique protocol identifier need not be a number, Unique Protocol Identification Number is defined in the final rule as "any unique identifier assigned to the protocol by the sponsor." We note that once a unique protocol identifier is entered on *ClinicalTrials.gov,* the same identifier cannot be assigned to another protocol for another clinical trial in the sponsor's *ClinicalTrials.gov* account. In cases in which multiple identifiers may have been assigned to a clinical trial (*e.g.,* a funding organization's grant number, a unique identifier established by another clinical trial registry), interpreting this term as an identifier "assigned by the sponsor" will remove any ambiguity for responsible parties about which identifier to submit as the unique protocol identifier for purposes of registration on *ClinicalTrials.gov.* We also expect that the unique protocol identifier would be readily available to the responsible party, whether the sponsor or a designated principal investigator who would have access to the protocol itself and/or be able to obtain the unique protocol identifier from the sponsor. Furthermore, these identifiers are often used in other clinical trial documentation, which will enable cross-referencing of information submitted to different data systems. To enable such cross-referencing, this data element will be publicly available on *ClinicalTrials.gov.*

(B) *Secondary ID.* In § 11.10(b)(34) of the NPRM, we defined the term, in part, as "[a]ny identification number(s) other than the organization's unique protocol identification number or NCT number that is assigned to the clinical trial . . ." Section 402(j)(2)(A)(ii)(IV)(bb) of the PHS Act expressly requires the submission of "other protocol identification numbers, if any," at the time of registration, but it does not define the term. We also proposed that the Secondary ID include the complete grant or contract number for any clinical trial that is funded, in whole or in part, by a U.S. Federal Government agency and "any unique clinical trial identification numbers assigned by other publicly available clinical trial registries" (*e.g.,* EudraCT in the EU). This requirement would enable users of *ClinicalTrials.gov* to identify Government-funded clinical trials. It also would assist agencies of the Department (including NIH, FDA, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality) to verify that clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted consistent with sections 402(j)(2) and (3) of the PHS Act and this part before the agency releases any remaining funding for a grant or provides funding for a future grant to such grantee as required under section 402(j)(5)(A)(ii) of the PHS Act of any agency of the Department that funds applicable clinical trials. In addition, the inclusion of grant and contract numbers for awards from other federal agencies (*e.g.,* Department of Veterans Affairs, Department of Defense) would facilitate efforts by the Secretary, as required under section 402(j)(5)(A)(iv) of the PHS Act, to consult with such other agencies and develop comparable procedures for the verification of compliance with the requirements of sections 402(j)(2) and (3) of the PHS Act. Finally, in order for users to interpret the various types of secondary ID information that might be provided in response to this requirement, we proposed to require responsible parties to submit "[a] description of the type of Secondary ID" for each secondary ID submitted. We stated that these descriptions should be brief but should clearly indicate the source of the identifier, *e.g.,* "U.S. NIH Grant Number" or "[XYZ] Registry Identifier." To facilitate data entry and improve comparability across registered clinical trials, we stated that we would include a list of several common identifier types in *ClinicalTrials.gov,* as well as permitting free-text entriesl (79 FR 69626).

Currently, *ClinicalTrials.gov* allows responsible parties to select from the following options: "US NIH Grant/ Contract Award Number," "Other Grant/Funding Number," "Registry Identifier," "EudraCT Number," and "Other Identifier." Responsible parties who select "Other Grant/Funding Number," "Registry Identifier," or "Other Identifier" are required to enter the name of the funding organization or a brief description of the identifier. One commenter supported the proposal to require responsible parties to provide the complete grant or contract number for any trial that is funded in whole or part by a U.S. Federal Government agency. We modify the proposed data element in the final rule for accuracy in a manner similar to the modifications made to the Unique Protocol Identification Number. To clarify that a secondary identifier need not be a number, Secondary ID is defined in the final rule, in part, as "[a]ny identifier(s) other than the organization's unique protocol identifier or NCT number that is assigned to the clinical trial, including any unique clinical trial identifiers assigned by other publicly available clinical trial registries." We will post the secondary ID publicly, as this information will enable users to locate additional information in other clinical trial registries as well as provide grant and contract numbers for awards from other Federal agencies.

(C) *U.S. Food and Drug Administration IND or IDE Number.* In § 11.10(b)(35) of the NPRM, we defined the Food and Drug Administration IND or IDE Number data element to include an indication whether or not there is an IND or IDE for the clinical trial (a yes/ no response) and, if so, each of the following elements: (1) "[n]ame or abbreviation of the FDA center with whom the IND or IDE is filed"; (2) "IND or IDE number assigned by the FDA center"; and (3) for an IND, "the IND serial number (as defined in 21 CFR 312.23(c), or any successor regulation), if any, assigned to the clinical trial." Section 402(j)(2)(A)(ii)(IV)(cc) of the PHS Act expressly requires the "Food and Drug Administration IND/IDE protocol number" to be submitted to *ClinicalTrials.gov* at the time of registration in *ClinicalTrials.gov,* but it does not define this term. FDA does not issue an "IND/IDE protocol number," as referred to in section 402(j)(2)(A)(ii)(IV)(cc) of the PHS Act; rather it issues an IND or IDE number. We therefore proposed to use the term "Food and Drug Administration IND or IDE number" to identify this data element on *ClinicalTrials.gov.* We also recognized that not all applicable clinical trials will be conducted under an IND or IDE (*e.g.,* because they are exempt). Because Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH) each issues IND or IDE numbers using a similar format, we expressed in the NPRM our belief that, for purposes of registration with *ClinicalTrials.gov,* a complete, unambiguous IND or IDE number must include the name of the FDA center that issued it. In addition, if several clinical trials are conducted under a single IND, each such clinical trial may have a different serial number assigned to it. We noted that any such serial number must also be specified to avoid confusion. However, the NPRM explained that if multiple serial numbers are assigned to a single IND (*e.g.,* to reflect different clinical trials, protocols, or protocol amendments), the responsible party should submit only the first serial number that corresponds to the clinical trial being registered (79 FR 69626).

Commenters addressed the Food and Drug Administration IND or IDE Number data element. One commenter suggested that the final rule remove the proposed requirement to provide the name or abbreviation of the FDA center with which the IND or IDE is filed. Another commenter requested clarification on whether submitting an IRB registration number in place of an IDE number or the FDA center information would be sufficient for clinical trials of nonsignificant risk devices subject to FDA abbreviated IDE requirements. We proposed requiring the FDA center name as a sub-element of the Food and Drug Administration IND or IDE Number data element because CDER, CBER, and CDRH all issue IND or IDE numbers using a similar format. We also recognize that not all applicable clinical trials will be conducted under an IND or IDE (*e.g.*, "IND-exempt" trials) and therefore would permit a responsible party to indicate that a particular trial is not being conducted under an FDA IND or IDE (*i.e.*, the responsible party would indicate "no" for this sub-element). We clarify that the FDA IND or IDE Number only refers to the number that is assigned by one of the FDA centers. Because FDA does not assign an IDE number for a clinical trial of a non-significant risk device subject to FDA-abbreviated IDE requirements nor does it issue an IDE for a clinical trial conducted outside of the United States, a responsible party for such trials should indicate "no" for the U.S. Food and Drug Administration IND or IDE Number data element. One commenter suggested that the final rule require information on whether a trial is being conducted under an IND or BLA for all trials conducted in the United States. As proposed under the NPRM, all responsible parties would be required to indicate whether an applicable clinical trial is being conducted under an IND or IDE, regardless of whether trial facility locations are within or outside the United States or both. We do not require the submission of information about BLAs for this data element because they are submitted to FDA only after trial completion, when a manufacturer is seeking to obtain a license for marketing a biological product, and so would not be available during trial registration. We note, however, that section 402(j)(5)(B) of the PHS Act requires submissions of BLAs to FDA to be accompanied by a certification (*i.e.*, Form FDA 3674) that all applicable requirements of this part have been met and to include a list of appropriate NCT numbers for applicable clinical trials used to support the BLA. Another commenter suggested that the final rule require the inclusion of an IND number or IND-exempt status of a trial to accommodate the determination of which trials quality for coverage of routine care costs of clinical trials under the Affordable Care Act in 42 U.S.C. 300gg–8. As noted in the NPRM, we do not intend to make the Food and Drug Administration IND or IDE Number available in the posted record. However, we note that this information would be readily accessible in the PRS to a responsible party for its own records and could be used by the responsible party to support this need. After consideration of these comments, we retain the proposed definition in final rule, but we clarify that it means "an indication of whether" there is an IND or IDE for the clinical trial. We also change the name of the data element to "U.S. Food and Drug Administration IND or IDE Number" for clarity, sinces other countries also have governmental agencies named "Food and Drug Administration" (*e.g.*, Korea).

(D) *Human Subjects Protection Review Board Status.* Section § 11.10(b)(36) of the NPRM defined this data element as "information to indicate whether a clinical trial has been approved by a human subjects protection review board or is exempt from human subjects protection review board approval. Human Subjects Protection Review Board Status must be listed as 'approved' if at least one human subjects protection review board has approved the clinical trial." While submission of this information is not required by section 402(j) of the PHS Act, we proposed to add this requirement pursuant to the authority given by section 402(j)(2)(A)(iii) of the PHS Act to modify the requirements for clinical trial registration information if such modification "improves and does not reduce such clinical trial information." We expressed in the NPRM our belief that submission of the Human Subjects Protection Review Board Status to *ClinicalTrials.gov* would improve, and not reduce, clinical trial information by indicating to users of the data bank whether a clinical trial registered on *ClinicalTrials.gov* is undergoing or has undergone review by a human subjects protection review board. Inclusion of this information would inform potential human subjects of whether the clinical trials they find on *ClinicalTrials.gov* have undergone at least one human subjects protection review board review, have received the necessary approvals for human subjects research from at least one human subjects protection review board, or were exempt from such review. We stated in the NPRM that the responsible party would be required to select from the following limited set of options intended to cover all possible statuses: "Request not yet submitted" (review board approval is required but has not yet been requested); "Submitted, pending" (review board approval has been requested but not yet granted); "Submitted, approved" (review board approval has been requested and obtained); "Exempt" (an exemption in accord with applicable law and regulation has been granted); "Submitted, denied" (review board has denied the approval request); and "Submission not required" (review board approval is not required because the study is not subject to laws, regulations, or applicable institutional policies requiring human subjects review). No "other" option was proposed. We requested comments on whether this menu of options adequately captured all possible review statuses for clinical trials that would be subject to this regulation (79 FR 69627).

The NPRM stated that the status would be listed as "approved" if at least one human subjects protection review board has approved the clinical trial. To clarify for users that the human subjects protection review board status pertains to only one human subjects protection review board, we would indicate that fact on *ClinicalTrials.gov* and instruct potential human subjects to communicate with the site-specific point-of-contact or the central contact for the clinical trial (included as part of the Facility Information data element that is submitted as part of clinical trial information under § 11.28(a)(2)(iii)(C)) in order to determine the status of human subjects protection review board review at other sites of interest. We indicated that we believe this approach will provide users with important information about human subjects review without burdening responsible parties with updating information on multiple sites (79 FR 69627). Some commenters proposed that the final rule require the submission of more detailed information for the Human Subjects Protection Review Board Status data element and display that information on the posted record, with one suggesting that public access to such information would be helpful for patients as well as for promoting the use of central IRBs for multicenter trials. As discussed, we believe that the proposed approach strikes the appropriate balance by providing users with the important information that at least one human subjects protection review board has reviewed and approved a trial without burdening responsible parties with the need to submit and update more detailed information for each board (up to one per facility). Therefore, we retain the proposed approach in the final rule.

We note that an applicable clinical trial could be registered prior to human subjects protection review board approval by indicating that the status is Request not yet submitted; Submitted, pending; or Exempt. If the status subsequently changes, the responsible party would be required, consistent with § 11.64(a)(1), to update the Human Subjects Protection Review Board Status data element not later than 30 calendar days after the change. If any IRB is still providing oversight for at least one site, the status of the trial would not be suspended even if such action is taken in relation to another site. We will continue to make available, as optional data elements, more detailed information about IRB approval, such as the name of the IRB, to support a responsible party's and/or an organization's tracking needs.

(E) *Record Verification Date.* Section § 11.10(b)(37) of the NPRM defined Record Verification Date as "the date upon which the responsible party last verified the clinical trial information in the entire *ClinicalTrials.gov* record for the clinical trial, even if no additional or updated information was submitted at that time." This data element is required by section 402(j)(2)(A)(ii)(IV)(cc) of the PHS Act to be submitted as part of clinical trial information at the time of registration, but it does not define the term. In the NPRM, we expressed our belief that the record verification date is intended to be submitted as a separate data element that indicates to users of the data bank how recently the information for a particular clinical trial was verified and, hence, whether it may be out of date. We stated our intent to collect and post publicly the Record Verification Date data element on *ClinicalTrials.gov* (79 FR 69628).

We proposed requiring responsible parties to include the Record Verification Date data element as part of the initial submission of clinical trial registration information to *ClinicalTrials.gov* and to update it any time the responsible party reviews the complete clinical trial record for accuracy, such as when making a periodic review of an entire clinical trial record. However, if the responsible party submits updates to one or more data elements without reviewing the accuracy of the rest of the record, the Record Verification Date data element would not be updated. We noted that the proposed approach would not require a responsible party to review records more frequently or regularly than would be needed in order to update submitted information as specified in § 11.64 (should the responsible party use this method to help ensure that updates are submitted on time), but it would require that the Record Verification Date be updated if the complete record was reviewed for accuracy during such an update (79 FR 69628).

One commenter requested that we delete the word "entire" from the definition so that the responsible party is not required to review all data in the record any time the responsible party reviews some of the information. We agree with the commenter's point that a responsible party is not required to review all data each time a record is accessed. We believe, however, that the proposed definition makes it clear that the record verification date needs to be updated only when the responsible party does review the entire record, not just part of the record. This data element allows users to determine when all of the data submitted in the record was last reviewed and verified by the responsible party. Therefore, we maintain the NPRM definition in the final rule, but we note that § 11.64 of the final rule specifies that "Record Verification Date must be updated any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months, even if no other updated information is submitted at that time."

(F) *Responsible Party Contact Information.* In § 11.10(b)(38) of the NPRM, we described Responsible Party Contact Information as "[a]dministrative information to identify and allow communication with the responsible party by telephone, email, and regular mail or delivery service. Responsible Party Contact Information includes the name, official title, organizational affiliation, physical address, mailing address, phone number, and email address of the individual who is the responsible party or of a designated employee of the organization that is the responsible party." Section 402(j)(1)(B) of the PHS Act requires the Secretary to develop a mechanism "by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information. . . ." Using the authority in section 402(j)(2)(A)(iii) of the PHS Act, we proposed to modify the requirements for clinical trial information submitted at the time of registration to require responsible parties to submit Responsible Party Contact Information. As noted in the NPRM, we believe that the addition of this information will improve and not reduce clinical trial information by providing a mechanism for the Agency to communicate with the responsible party about submitted information, which can improve its quality, accuracy, and completeness. We noted that we do not intend to post the physical address, mailing address, phone number or email address of the responsible party (79 FR 69628). We received no comments on this data element and therefore maintain it in the final rule. In general, we intend to post the name of the responsible party if the responsible party is an individual (*e.g.,* a sponsor-investigator who holds the IND or IDE for a clinical trial or a designated principal investigator). We would post the name of the responsible party, along with the Responsible Party, by Official Title data element as specified in § 11.28(a)(2)(iii)(B) of the final rule, which section 402(j)(2)(A)(ii)(III)(bb) of the PHS Act requires to be made publicly available. We believe that the posting of the individual's name is necessary to avoid ambiguity; for example, if the responsible party is a university professor, there may be a number of individuals with the same title and affiliation (professor of medicine at ABC University). Posting the name of the individual when an individual is the responsible party would also be consistent with posting the name of the entity when an entity is the responsible party of an applicable clinical trial. The Responsible Party Contact Information data element would be required to be updated as specified in § 11.64.

Data elements that were suggested in public comments but not incorporated into the final rule are discussed below.

Bioequivalence and Bioavailability. One commenter requested the addition of data elements to identify bioequivalence and bioavailability studies and to indicate specific biomarkers relevant to the population studied. We note that *ClinicalTrials.gov* currently offers an optional registration data element, Study Classification, that includes both "Bio-equivalence" and "Bio-availability" as options. Biomarkers that are the focus of a study may be listed in the Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study data element specified in proposed § 11.48(a)(1)(ix) and defined in proposed § 11.10(b)(9). We also note that biomarkers may be described in the context of outcome measures that are evaluated in the clinical trial. Otherwise, responsible parties could provide such information voluntarily as part of an optional data element (*e.g.,* Detailed Description). Because responsible parties can submit this information using optional data elements, and consistent with our goal to minimize the number of required data elements, we do not require the submission of this information in the final rule. We understand the growing interest in and research on biomarkers and will continue to evaluate this topic and ways to further optimize the collection, retrieval, and display of such information.

Individual Participant Data (IPD) Availability. One commenter requested that the final rule include an optional data element for indicating whether IPD or CSRs are being made available to others and, if so, the location of the data and contact information. In December 2015, *ClinicalTrials.gov* added the following optional data elements that allow responsible parties to provide information about their plans for sharing IPD and to describe where data sets and/or study documents are available: Plan to Share Data? and Available Study Data/Documents. Because responsible parties can choose to submit this information using the optional data elements, and consistent with our goal to minimize the number of required data elements, we do not include these data elements in the final rule.

Other Trial Characteristics. Several commenters suggested that whether a registered trial is "for profit" should be clearly labeled on the posted record on *ClinicalTrials.gov.* We are not aware of any standard approaches for defining a trial's profit status (*e.g.,* "for profit" or "non-profit") and the commenters did not suggest any operational definitions. In addition, there are many features of a trial's sponsor that may be of interest to potential participants, as well as those interested in the study's results; *ClinicalTrials.gov* can help identify the trial and its sponsor but cannot provide all potentially relevant information. One other commenter recommended adding a data element that could be used for searching for trials of genetic therapies. We note that the Intervention Type data element defined in § 11.10(b)(13) includes a "genetic" (including gene transfer, stem cell and recombinant DNA) option that a responsible party could choose to identify a genetic therapy intervention. For these reasons, we are not adding additional data elements to include other trial characteristics, but we will consider providing an Advanced Search feature in the future that would allow users to search *ClinicalTrials.gov* for registered studies by Intervention Type.

Schedule of Events. One commenter suggested that the Agency consider adding a "schedule of events" data element that would provide information for participants about the medical care that will be covered in a study. While we understand that this information could be important for a potential participant, we believe it is more appropriate for this information be provided by the study contact at the time that potential participants and/or their health care providers are seeking further information about the study. Accordingly, we are not including this data element in the final rule.

§ 11.28(b)—Pediatric Postmarket Surveillance of a Device Product That Is Not a Clinical Trial

Overview of Proposal

(b) *Data elements required to register a pediatric postmarket surveillance of a device product that is not a clinical trial.* Proposed § 11.28(b) specified the clinical trial information that must be submitted to *ClinicalTrials.gov* to register a pediatric postmarket surveillance of a device that is not a clinical trial, as defined in this part, but is required to be registered under proposed § 11.22. Section 801(c) of FDAAA recognizes that not all of the clinical trial information specified in section 402(j) of the PHS Act or proposed in this rule will apply to all pediatric postmarket surveillances of a device and directs the Secretary to issue guidance explaining how the registration and results information submission provisions of section 402(j) of the PHS Act apply to a pediatric postmarket surveillance of a device that is not a clinical trial. As stated in the NPRM, the Agency intended for the discussion of the proposed sections related to pediatric postmarket surveillances of a device to provide draft guidance. In 21 CFR 822.3, "postmarket surveillance" is defined as the "active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device." The Agency interpreted a pediatric postmarket surveillance of a device as a postmarket surveillance of a device used in a pediatric population (*i.e.,* patients who are 21 years of age or younger at the time of diagnosis or treatment) (see 21 U.S.C. 360j(m)(6)(c)). The clinical trial information specified in proposed § 11.28(a) and defined in proposed § 11.10(b) would apply to any pediatric postmarket surveillance of a device that is a clinical trial (*i.e.,* Study Type would be "interventional"). However, because not all pediatric postmarket surveillances under section 522 of the FD&C Act are clinical trials, as defined in this part, many of the data elements listed in proposed § 11.28(a) or the definitions proposed in § 11.10(b) may not apply. Therefore, proposed § 11.28(b) specified a more limited set of data elements required to register a pediatric postmarket surveillance of a device that is not a clinical trial; moreover, it also modified the definitions of certain data elements that were defined in proposed § 11.10(b) (79 FR 69629).

In general, the proposed definitions of these data elements were consistent with the definitions of the named data elements in proposed § 11.10(b); however, we had modified them, where appropriate, to better match the characteristics of pediatric postmarket surveillances of a device that are not clinical trials. For example, Study Start Date, which was defined in proposed § 11.10(b)(16) for a clinical trial as "the estimated date on which a clinical trial will be open to enrollment of human subjects, or the actual date on which the first human subject was enrolled," was defined in proposed § 11.28(b)(1)(xi) as the "date on which FDA approves the postmarket surveillance plan, as specified in 21 CFR 822.19(a) (or any successor regulation)." Similarly, the definition of Completion Date in section 402(j)(1)(A) of the PHS Act and proposed § 11.10(b)(17) generally would not apply to a pediatric postmarket surveillance of a device that is not a clinical trial; therefore, in proposed § 11.28(b)(1)(xii) we proposed to require submission of the Completion Date data element, which was defined as "[t]he estimated date on which the final report summarizing the results of the pediatric postmarket surveillance of a device is expected to be submitted to FDA. Once the final report has been submitted, the actual date on which the final report is submitted to FDA." The Agency considered the proposed list of required data elements for a pediatric postmarket surveillance of a device that is not a clinical trial to be the most inclusive set of data elements that could be expected to apply to all pediatric postmarket surveillances of a device that are not clinical trials, regardless of the design of the surveillance. The proposed required information would allow users to access records of pediatric postmarket surveillances of a device that are not clinical trials by conducting searches using a number of relevant criteria, retrieve basic descriptive information about the surveillances, and find a point-of-contact for additional information. We did not propose the submission of those data elements listed under section 402(j)(2)(A)(ii) of the PHS Act that are not expected to apply to all pediatric postmarket surveillances of a device that are not clinical trials. For example, Study Phase is relevant only to clinical trials involving drugs. The specific elements of Study Design (*e.g.,* Interventional Study Model, Allocation, Masking, Single Arm Controlled?) would not apply to most studies that are not interventional clinical studies (*i.e.,* clinical trials). Eligibility Criteria, Age, and Gender may not be defined specifically for the study population in a pediatric postmarket surveillance of a device that is not a clinical trial. Enrollment would not be relevant to a pediatric postmarket surveillance of a device that takes the form of a literature review. We noted that we expect that some information about the study design and relevant study population would be included in the brief summary of the pediatric postmarket surveillance of a device. We invited comments on alternative approaches for specifying the registration requirements for a pediatric postmarket surveillance of a device that is not a clinical trial (79 FR 69629).

Comments and Response

One commenter suggested that the registration data elements required to be submitted for a pediatric postmarket surveillance of a device that is not a clinical trial in proposed § 11.28(b) be replaced in the final rule with the same set of data elements required for clinical trials as specified in proposed § 11.28(a). The Agency disagrees with this suggestion. As described in the preamble, not all pediatric postmarket surveillances of a device product under section 522 of the FD&C Act are clinical trials. For such pediatric postmarket surveillances of a device product, many of the data elements for clinical trials listed in proposed § 11.28(a) and defined in proposed § 11.10(b) would not apply. Therefore, we specified in proposed § 11.28(b), and retain in the final rule, a limited set of registration data elements that would more likely apply across all pediatric postmarket surveillances of a device product, and we modified the definitions in proposed § 11.10(b) accordingly.

Final Rule

Taking into consideration the commenter's suggestions and the statutory requirements for what constitutes clinical trial registration information, § 11.28(b) of the final rule retains the data elements proposed in the NPRM but modifies some of the names and definitions to improve clarity and for consistency with the data elements named in § 11.28(a) and defined in § 11.10(b) of the final rule. Section 11.28(b) of the final rule identifies the structured information, or data elements, that constitute clinical trial information that a responsible party must submit in order to register a clinical trial. While the full set of data elements from the NPRM is maintained in the final rule, we have modified some of the names and definitions. For example, we have clarified that "device" means "device product" and the proposed name of Whether the Study is a Pediatric Postmarket Surveillance of a Device data element in § 11.28(b)(1)(v) of the NPRM has been renamed "Pediatric Postmarket Surveillance of a Device Product" throughout the final rule (*i.e.,* in §§ 11.10(b)(8), 11.28(a), 11.28(b), 11.60(b)(2)(i)(B)) for clarity and convenience, but the proposed definition is maintained in the final rule. Conversely, while the name of the Unique Protocol Identification Number data element has been retained, the definition has been modified from "the unique identification number" to "the unique identifier" for accuracy (*i.e.,* is not limited to numbers).

As set forth in § 11.28(b) of the final rule, to register a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party must provide the following data elements: (1) Brief Title; (2) Official Title; (3) Brief Summary; (4) Study Type; (5) Pediatric Postmarket Surveillance of a Device Product; (6) Primary Disease or Condition Being Studied, or the Focus of the Study; (7) Intervention Name(s); (8) Other Intervention Name(s); (9) Intervention Description; (10) Intervention Type; (11) Study Start Date; (12) Primary Completion Date; (13) Name of the Sponsor; (14) Responsible Party, by Official Title; (15) Contact Information; (16) Unique Protocol Identification Number, if any; (17) Secondary ID; (18) Human Subjects Protection Review Board Status; (19) Record Verification Date; and (20) Responsible Party Contact Information. Consistent with the elaboration of these data elements in Section IV.B.4 of the preamble, for a pediatric postmarket surveillance of a device product that is not a clinical trial the Study Type must be designated as "observational" and Pediatric Postmarket Surveillance of a Device Product must indicate "yes."

In addition, for a pediatric postmarket surveillance of a device product that is not a clinical trial, we recommend that the responsible party submit any other registration information data elements that are consistent with the surveillance design and are capable of being accepted by *ClinicalTrials.gov.* For example, for a pediatric postmarket surveillance of a device product that takes the form of a prospective observational study, information such as the location(s) of the surveillance, its eligibility criteria, the recruitment status, and its outcome measures would also be relevant and should be submitted. We believe the public would be best served if additional descriptive information about these pediatric postmarket surveillances of a device product were included in the data bank, but, given the lack of experience to date, we cannot at this time specify what additional information would be relevant to a particular type of pediatric postmarket surveillance of a device product that is not a clinical trial.

§ 11.28(c)—Expanded Access Records

Overview of Proposal

(c) *Data elements required to create expanded access records.* Proposed § 11.28(c) described the clinical trial information that must be submitted to *ClinicalTrials.gov* to create an expanded access record when a responsible party registers an applicable drug clinical trial that studies an unapproved drug or unlicensed biological product that is available via an expanded access program under section 561 of the FD&C Act to those who do not qualify for enrollment in the clinical trial. However, because expanded access programs do not share all of the characteristics of clinical trials, as defined in this part, many of the data elements listed in proposed § 11.28(a) or their definitions in proposed § 11.10(b) do not apply. Therefore, proposed § 11.28(c) specified a limited set of data elements required to create an expanded access record; moreover, it also modified the definitions of certain data elements in proposed § 11.10(b). Overall, in the NPRM we considered the proposed set of data elements required to create an expanded access record to be the most inclusive that would be relevant to all expanded access programs (other than individual-patient access), regardless of design, and helpful to users of *ClinicalTrials.gov* who wish to determine whether they may be eligible to receive an investigational drug through an expanded access program and to obtain additional information about such access. The descriptions of the data elements in the NPRM generally paralleled the definitions of the data elements in proposed § 11.10(b) that are required to be submitted when registering a clinical trial under proposed § 11.28(a), but were modified in proposed § 11.28(c) to refer to expanded access programs rather than clinical trials and to be limited to expanded access programs for drugs and biologics. One data element that was not defined in proposed § 11.10(b) but is required to be submitted for expanded access records only is the Expanded Access Status data element. We invited comments on whether the proposed list of options for this data element was sufficient to describe the status of an expanded access program (79 FR 69630).

We proposed requiring the submission of information to create an expanded access record using the statutory authority in section 402(j)(2)(A)(iii) of the PHS Act, which allows the Secretary by regulation to modify the requirements for clinical trial registration information if the Secretary provides a rationale why such a modification "improves and does not reduce such clinical trial information." Information about the availability of expanded access is a data element that a responsible party is required to submit under section 402(j)(2)(A)(ii)(II) of the PHS Act and thus meets the definition of "clinical trial information" as that term is used in section 402(j)(1)(A)(iv) of the PHS Act. We noted in the NPRM that we think these additional data elements describing expanded access would improve and not reduce clinical trial information by providing users with more complete and consistent information about expanded access programs for drugs studied in applicable clinical trials than would be available pursuant to section 402(j)(A)(ii)(II)(gg) of the PHS Act alone. We further concluded that the clinical trial information required under proposed § 11.28(c), to be submitted by creating a separate expanded access record in *ClinicalTrials.gov,* under section 402(j)(2)(B)(iv) of the PHS Act would help ensure that the public can more easily use the data bank to determine whether there is expanded access to a drug and to compare different expanded access programs. In addition, this approach was consistent with the practice followed prior to the enactment of FDAAA, when those registering trials in compliance with FDAMA submitted expanded access information in the form of expanded access records on *ClinicalTrials.gov.* We proposed that in the rare instance in which an expanded access program for a drug met all of the elements of an applicable drug clinical trial, the expanded access program would have to be registered as an applicable drug clinical trial (79 FR 69630). In developing the NPRM, we considered alternative approaches, such as requiring the responsible party to submit the name, phone number, and email address of a point-of-contact or Web site for information about the expanded access program for each clinical trial of a drug that has such a program. However, we concluded that this approach would not ensure that complete information is available and, by including such information as part of clinical trial registration information, we can better ensure that the information is kept up-to-date as required in proposed § 11.64. Another alternative we considered was to require responsible parties to enter the additional data elements describing expanded access with every applicable clinical trial of a drug or biological product for which expanded access is available. Under our proposal, however, in situations in which multiple applicable clinical trials study the same drug that is available via the expanded access program, the expanded access record would be submitted only once. Thereafter, any responsible party could link the expanded access record to the clinical trial record(s) using the NCT number assigned to the expanded access record, thereby reducing the burden a responsible party faces when providing information about expanded access for multiple records (79 FR 69631).

As explained in Section IV.B.4 of the NPRM, in the discussion of the Availability of Expanded Access data element, the expanded access record generated on *ClinicalTrials.gov* pursuant to the submission of the data elements at proposed § 11.28(c) would be assigned its own NCT number and would be searchable and retrievable independent of the record(s) for the clinical trial(s) that study(ies) the drug or biological product for which expanded access is offered. To allow *ClinicalTrials.gov* to establish a link between the expanded access record and the clinical trial record(s), the responsible party(ies) for any applicable clinical trials of the drug available via expanded access would be required to include the NCT number that is assigned to the expanded access record as part of the registration information submitted for that clinical trial. In this way, the expanded access record could be linked in this fashion to multiple applicable clinical trials that study the drug or biological product that is available via the expanded access program. We sought comments on this proposed approach.

We also proposed that expanded access information for a medical device that was studied in an applicable device clinical trial could be submitted voluntarily under section 402(j)(4)(A) of the PHS Act to create an expanded access record for the device. (79 FR 69630) We further proposed that if a responsible party chose to submit this information, the responsible party would be required to submit all of the data elements that are required for expanded access to a drug in § 11.28(c), and that such expanded access records for investigational devices would be required to be updated in accordance with § 11.64(b)(1)(v).

Comments and Response

We received comments addressing the proposed content of an expanded access record. A commenter suggested that NIH and FDA should streamline and standardize expanded access information for patients and that NIH should collect and post the results obtained through expanded access programs on *ClinicalTrials.gov.* A commenter proposed linking expanded access records to the FDA application forms for expanded access programs. Section 11.28(c) of the NPRM represented our efforts to develop a streamlined and standardized approach to presenting information on *ClinicalTrials.gov* about expanded access programs. The proposed set of data elements represents, for the most part, a subset of the registration data elements required for an applicable clinical trial of a drug under proposed § 11.28(a). These proposed data elements were selected to represent key information that would generally apply across all expanded access programs. We stated in the NPRM that these data elements would allow *ClinicalTrials.gov* to display a structured summary about each expanded access program in a consistent format that would allow users to review important information quickly and easily (*e.g.,* eligibility criteria, disease or condition, intervention name and description). Regarding the suggestion to require the submission of results from expanded access use, as discussed in Section IV.A.5, we have concluded that use of an investigational drug product (including a biological product) under expanded access will not be considered an applicable clinical trial. Therefore, no expanded access use of an investigational drug product (including a biological product) will be subject to the results information submission requirements of this rule. We will consider providing links to additional resources about expanded access such as FDA application forms on the *ClinicalTrials.gov* public Web site, as suggested.

Final Rule

Taking into consideration the commenters' suggestions and the statutory requirements for what constitutes clinical trial registration information, § 11.28(c) of the final rule modifies the set of data elements from the NPRM that a responsible party must submit in order to create an expanded access record as required in § 11.28(a)(2)(ii)(H) of the final rule. Some of the data elements in § 11.28(c) that have been modified from what was proposed address the modification described in section IV.B.4 of this preamble in the discussion of the Availability of Expanded Access data element, which requires submission of an expanded access record for all expanded access types, including when expanded access is available for individual patients, including emergency use. Other modifications include some of the names and definitions of the proposed data elements to improve clarity and consistency with the data elements named in § 11.28(a) and defined in § 11.10(b) of the final rule, including the clarification that "drug" means "drug product" and that "device" means "device product". In addition, we provide further elaboration on the purpose of some data elements and how a responsible party can meet the data element requirements. Section 11.28(c) of the final rule also clarifies that expanded access records are only required to be created and updated by a responsible party who is both the manufacturer of the investigational drug product (including biological product) that is available through expanded access and the sponsor of an applicable clinical trial of that investigational drug product (including biological product), as specified in §§ 11.10(b)(28) and 11.28(a)(2)(ii)(H) of the final rule. Finally, we exclude from the final rule the proposed provision regarding the voluntary submission of expanded access information for a medical device under section 402(j)(4)(A) of the PHS Act, and we provide a further explanation below.

The Expanded Access Type data element, which was not proposed in the NPRM, is defined in § 11.28(c)(1)(x) of the final rule as "[t]he type(s) of expanded access for which the investigational drug product (including a biological product) is available as specified in § 11.10(b)(28)." For this data element, responsible parties would be required to select one or more options from the following limited set: "individual patient" (*i.e.*, expanded access for individual patients, including for emergency use, as specified in 21 CFR 312.310), "intermediate" (*i.e.*, expanded access for intermediate-size patient populations, as specified in 21 CFR 312.315), or "treatment use" (*i.e.*, expanded access for widespread treatment use under a treatment IND or treatment protocol, as specified in 21 CFR 312.320). As described in section IV.B.4 of this preamble, in the discussion of the Availability of Expanded Access data element, the final rule expands the proposed requirement to provide expanded access records for all types of expanded access available for an unapproved drug product (including a biological product). In light of this expansion, the Expanded Access Type data element is required to indicate the particular type(s) of expanded access under which an investigational drug product (including a biological product) is available. Additionally, the submission of certain expanded access record data elements specified in § 11.28(c)(2) are not required if the Expanded Access Type indicates that expanded access is available only for individual patients, including for emergency use. Thus, the Expanded Access Type data element facilitates identifying which information must be provided, specific to the type of availability of expanded access. For these reasons, this new registration data element is authorized by section 402(j)(2)(A)(ii) of the PHS Act because requiring it improves and does not reduce the clinical trial information.

While the other required data elements from the NPRM are maintained in the final rule, we have modified some of the names and definitions to be consistent with other modifications throughout this final rule. For example, the proposed Gender data element in § 11.28(c)(2)(ii) of the NPRM is renamed "Sex/Gender" here and throughout the final rule to be consistent with the same modification described in section IV.B.4 of this preamble and § 11.28(a)(2)(ii) of the final rule. Conversely, while the name of the Unique Protocol Identification Number data element is maintained, the definition has been modified from "the unique identification number" to "the unique identifier" for accuracy (*i.e.*, is not limited to numbers) and the explanation modified to explain it can also be an identifier of the expanded access record. Specifically, if the sponsor did not assign a unique identifier to the availability of its investigational drug product (including a biological product) for expanded access use, an identifier for the expanded access record must be provided. This identifier is composed of numbers and/or letters and is needed to uniquely identify an expanded access record in the PRS prior to submission and assignment of an NCT number. The Agency will provide additional instructions at *https://prsinfo.clinicaltrials.gov* (or successor site) to assist sponsors in creating a unique identifier for the expanded access record if the sponsor did not assign an identifier to the expanded access. Similarly, instructions will also be available at *https://prsinfo.clinicaltrials.gov* (or successor site) for sponsors needing to create a Brief Title as specified in § 11.28(c)(1)(i), which is used for identification of the expanded access record in the PRS and on the publicly posted study record.

As set forth in § 11.28(c) of the final rule, if expanded access is available for an intermediate-size patient population as specified in 21 CFR 312.315) or through a treatment IND or treatment protocol (as specified in 21 CFR 312.320), a responsible party who is both the manufacturer of an investigational drug product (including a biological product) that is available through expanded access and the sponsor of an applicable clinical trial of that investigational product must provide the following data elements to create an expanded access record: (1) Brief Title; (2) Official Title; (3) Brief Summary; (4) Study Type (which is "expanded access" for this type of record); (5) Primary Disease or Condition; (6) Intervention Name(s); (7) Other Intervention Name(s); (8) Intervention Description; (9) Intervention Type (which is typically "drug"), (10) Expanded Access Type; (11) Eligibility Criteria; (12) Sex/Gender; (13) Age Limits; (14) Expanded Access Status; (15) Name of the Sponsor; (16) Responsible Party, by Official Title; (17) Contact Information; (18) Unique Protocol Identification Number; (19) Secondary ID; (20) U.S. Food and Drug Administration IND Number; (21) Record Verification Date; and (22) Responsible Party Contact Information.

If expanded access is only available for individual patients, including for emergency use as specified in 21 CFR 312.310, then only the following data elements are required: (1) Brief Title; (2) Brief Summary; (3) Study Type; (4) Intervention Name; (5) Intervention Type; (6) Expanded Access Type; (7) Expanded Access Status; (8) Name of Sponsor; (9) Responsible Party, by Official Title; (10) Contact Information; (11) Unique Protocol Identification Number; (12) U.S. Food and Drug Administration IND number, if applicable; (13) Record Verification Date; and (14) Responsible Party Contact Information. This more limited set of expanded access information is sufficiently detailed to address the availability of an investigational drug product (including biological product) under individual patient expanded access.

If information necessary to complete certain data elements required for submitting an expanded access record under § 11.28(c)(1)–(4) are unknown to the responsible party because the expanded access availability is managed by a different entity, the responsible party will need to consult with NIH concerning those data elements before submitting the expanded access record. Instructions for contacting NIH will be available at *https://prsinfo.clinicaltrials.gov* (or successor site). We also note that the definition of Official Title specified in § 11.28(c)(1)(ii) has been clarified to indicate it only needs to be provided if one exists (*i.e.,* if there is an official title then it must be provided; if there is not an official title, the data element does not need to be provided). Similarly, the U.S. Food and Drug Administration IND Number data element has been modified to allow a responsible party to specify whether the expanded access is being conducted under an IND, but to allow for certain elements related to the IND to be provided "if applicable".

Expanded Access Status is another data element that is required to be submitted only for expanded access records and is not defined in § 11.10(b). It is defined in § 11.28(c)(2)(iv) of the final rule to mean "[t]he status of availability of the investigational drug product (including a biological product) through expanded access." When submitting this data element, responsible parties are required to select from the following limited set of options for describing the current status of availability of the investigational drug product through the expanded access program: "Available" (expanded access is currently available), "No longer available" (expanded access was available previously but is not currently available and is not expected to be available in the future), "Temporarily not available" (expanded access was previously available, is not currently available, but is expected to be available in the future), and "Approved for marketing" (expanded access was available previously but is not currently available because the drug or device has been approved, licensed, or cleared by FDA).

We have further considered the proposal regarding the voluntary submission of expanded access information under section 402(j)(4)(A) of the PHS Act for unapproved or uncleared device products that are studied in an applicable device clinical trial and have decided not to include this provision in the final rule under § 11.60. The Availability of Expanded Access data element defined in § 11.10(b)(28) and specified in § 11.28(a)(2)(ii)(H) of the final rule is a data element that is specific to the availability of expanded access for an applicable drug clinical trial of an investigational drug product (including a biological product). Similarly, the obligations in § 11.28(c) to create an expanded access record are, consistent with section 402(j)(2)(A)(ii)(II)(gg) of the PHS Act, are specific to the provision of information when expanded access to an investigational drug product (including a biological product) is available under section 561 of the FD&C Act and 21 CFR 312.310 (for individual patients, including for emergency use), 21 CFR 312.315 (for an intermediate-size patient population), or 21 CFR 312.320 (under a treatment IND or treatment protocol). Therefore, for the purposes of the voluntary submission of expanded access information under section 402(j)(4)(A) of the PHS Act and § 11.60 for unapproved or uncleared device products that are studied in an applicable device clinical trial, "complete clinical trial information" does not include information about the availability of expanded access for the investigational device product.

We note that a responsible party for an applicable device clinical trial could choose to create an expanded access record for the investigational device product being studied in that trial if the investigational product is being made available under section 561 of the FD&C Act and 21 CFR 812.36. We intend to provide additional information at *https://prsinfo.clinicaltrials.gov* (or successor site) to clarify which data elements would apply in such a situation.

5. 11.35—By when will the NIH Director post clinical trial registration information submitted under § 11.28?

Overview of Proposal

According to section 402(j)(2)(D)(i) of the PHS Act, for applicable clinical trials, NIH is to post registration information not later than 30 days after the information is submitted. In the NPRM, we proposed in § 11.35(a) that NIH will post publicly the clinical trial registration information, except for certain administrative data, "not later than 30 calendar days after the responsible party has submitted such information in accordance with § 11.24 of this part" (79 FR 69631).

For an applicable device clinical trial of a device that was previously cleared or approved by FDA, section 402(j)(2)(D)(ii)(II) of the PHS Act requires registration information to be posted "not later than 30 days after" results information is required to be posted. The Agency interpreted section 402(j)(2)(D)(ii)(II) of the PHS Act as providing a deadline by which such registration information must be posted. The Agency considered the requirement to post registration information "not later than 30 days after [results information] is required to be posted" to be the last possible date on which it may post registration information and that it is permissible to post registration information prior to the deadline. The NPRM at § 11.35(b)(1) proposed that for an applicable device clinical trial of a device that was previously approved or cleared, NIH will publicly post the clinical trial registration information, except for certain administrative data, not later than 30 calendar days after clinical trial results information is required to be posted in accordance with proposed § 11.52 (79 FR 69631).

Section 402(j)(2)(D)(ii)(I) of the PHS Act stipulates that for an applicable device clinical trial of a device that has not previously been cleared or approved, registration information must be posted publicly not earlier than the date of clearance or approval of the device and not later than 30 days after such date. Proposed § 11.35(b)(2) reflected this statutory provision by stating that for an applicable device clinical trial of a device that has not been previously approved or cleared, "NIH will post publicly at *ClinicalTrials.gov* the clinical trial registration information, except for certain administrative data, not earlier than the date of FDA approval or clearance of the device, and not later than 30 calendar days after the date of such approval or clearance." In the NPRM, we acknowledged that while postponing the posting of clinical trial registration information for applicable device clinical trials for a device that previously has not been approved or cleared may protect the commercial interests of device manufacturers, there are a number of situations in which those who conduct such clinical trials may prefer to make such information publicly available in the data bank prior to the time frames specified by section 402(j) of the PHS Act. Therefore, we invited comments from the public on how, given the statutory language of Section 402(j)(2)(D)(ii)(I) of the PHS Act, the Agency may address the concerns of sponsors and responsible parties who wish to have clinical trial registration information for applicable device clinical trials of devices that previously have not been approved or cleared made publicly accessible in *ClinicalTrials.gov* when the responsible party so chooses (79 FR 69576).

In order to help NIH meet the posting deadline and identify the set of applicable device clinical trials for which registration information must be posted after approval or clearance of a device, the NPRM included a requirement in proposed § 11.64(b)(2) for the responsible party to update the U.S. FDA Approval, Licensure, or Clearance Status data element not later than 15 calendar days after a change in status has occurred. The responsible party would be required to update that data element for all applicable device clinical trials that study a device that was approved or cleared (79 FR 69631).

Comments and Response

We received comments on the specific question of when NIH should post clinical trial registration information. Some commenters supported and some opposed the proposed approach to determining which devices would be able to take advantage of the delayed posting available to devices that have not been previously approved or cleared. This topic is addressed in more detail in Section IV.B.4 of this preamble.

Some commenters indicated they did not support the delayed posting of registration information for devices that have not been previously cleared or approved. Delayed posting is outlined in Section 402(j)(2)(D)(ii)(I) of the PHS Act, which says that the Agency may not post publicly clinical trial registration information before the date of clearance or approval for an applicable device clinical trial of a device that was not previously cleared or approved. Section 11.35(b)(2) of the NPRM, and the final rule at § 11.35(b)(2)(i), reflect this limit. Other commenters argued that the delayed posting of clinical trial registration information provision in the statute should not be understood as a bar to consensual disclosure of such information if a device sponsor wishes to waive the right to delayed posting. The commenters noted that under circumstances where a party wishes to waive a statutory right, and that waiver would not frustrate the public purpose of that statute, courts have acknowledged that statutory rights intended to protect individual rights may be waived by the persons for whom the statute provides protection.

We agree with views expressed by commenters that because the delayed posting of registration information benefits the responsible party, the responsible party should be able to choose to authorize the Agency to make registration information available earlier. There may be any number of reasons a responsible party would wish to opt out of the delayed posting of registration information, such as to enhance patient enrollment or to meet the requirements for consideration by a journal abiding by ICMJE policy [Ref. 2]. Although Section 402(j)(2)(D)(ii)(I) of the PHS Act provides that the Director of NIH "shall" ensure that clinical trial information for an applicable device clinical trial of an unapproved or uncleared device is not posted on *ClinicalTrials.gov* earlier than the date of clearance or approval of the device, section 402(j)(2)(A)(iii) of the PHS Act gives the Secretary authority to modify by regulation the requirements for clinical trial information under paragraph (2), which includes the delayed posting provision in 402(j)(2)(D)(ii), so long as a rationale is provided for why the modification improves and does not reduce such clinical trial information. The Agency believes that allowing the responsible party to authorize that clinical trial registration information that would otherwise fall under the delayed posting provision be publicly posted prior to approval or clearance of the product would improve and not reduce such clinical trial information by making it accessible to the public earlier. This approach would strike the proper balance between affording the statutory protections of delayed disclosure to those responsible parties that would like to take advantage of it while promoting transparency of clinical trial registration information by allowing responsible parties to authorize earlier posting.

Pursuant to section 402(j)(2)(A)(iii) of the PHS Act, we are adding a new provision at § 11.35(b)(2)(ii) to incorporate this option for a responsible party to authorize early posting as well as a specific data element in § 11.28(a)(2)(i)(Q) that will be the mechanism through which a responsible party can indicate to the Director that it is authorizing the Director to publicly post its clinical trial registration information prior to U.S. FDA approval or clearance of the device product. See further discussion in this Section describing the final rule as well as in Section IV.B.4 of this preamble.

Final Rule

We have taken into consideration the commenters' suggestions and the statutory requirements for posting registration information in developing § 11.35 of the final rule. Section 11.35(a) states that the Director will post publicly at *ClinicalTrials.gov* the clinical trial registration information for an applicable drug clinical trial not later than 30 calendar days after the responsible party has submitted such information, as specified in § 11.24.

Section 11.35(b)(1), which covers posting of registration information for an applicable device trial of a device product that has been previously approved or cleared, has been modified from the NPRM for clarity. We have added the phrase "as soon as practicable" to indicate that NIH will post registration information for an applicable device clinical trial of a device product that previously was approved or cleared "as soon as practicable, but not later than" the statutory deadline outlined in section 402 (j)(2)(D)(ii)(II) or successor statute. Section 402(j)(2)(D)(ii)(II) stipulates that clinical trial registration information for an applicable device clinical trial of a device that was previously cleared or approved will be posted "not later than 30 days after the clinical trial information under paragraph (3)(C) is required to be posted by the Secretary." The information referred to by "in paragraph (3)(C)" is basic results information. The additional phrase of "as soon as practicable" clarifies in the regulatory language the NIH's intent, described in the NPRM, to post registration information for such applicable device clinical trials as soon as practicable after submission, but not later than 30 calendar days after clinical trial results information is required to be posted. Posting this information prior to the deadline is consistent with the objectives of expanding the registry and results data bank by rulemaking, facilitating enrollment in clinical trials, and providing a mechanism to track subsequent progress of clinical trials. Conversely, waiting to post registration information for applicable device clinical trials of device products that were previously approved or cleared until after results information is required to be posted would delay access to information about such clinical trials and would eliminate the possibility for the data bank to be used to facilitate enrollment in such trials and to allow the public to track such trials while they are ongoing. We have also clarified that "device" means "device product."

Section 11.35(b)(2) covers posting of registration information for an applicable device trial of a device product that has not been previously approved or cleared. Proposed § 11.35(b)(2) has been separated in the final rule into § 11.35(b)(2)(i) and § 11.35(b)(2)(ii). In these sections, we have clarified that "device" means "device product." Additionally, § 11.35(b)(2)(i) adds a reference to the exception in § 11.35(b)(2)(ii) for earlier posting of registration information by the Director if authorized by the responsible party.

New § 11.35(b)(2)(ii) allows a responsible party for an applicable clinical trial that is initiated on or after the effective date of the rule to indicate to the Director, prior to the date of approval or clearance of the device product, that it is authorizing the Director to publicly post its clinical trial registration information that would otherwise be subject to delayed posting as specified in paragraph (b)(2)(i) prior to the date of FDA approval or clearance of the device product. Upon notification, in the form of the responsible party's submission of the Post Prior to U.S. FDA Approval or Clearance data element under § 11.28(a)(2)(i)(Q), the Director will post the clinical trial registration information, except for certain administrative data, as soon as practicable. Additionally, the Director intends to follow the timelines established by section 402(j)(2)(D)(i) of the PHS Act of posting the clinical trial registration information not later than 30 days after such submission. While this section of the statute refers to applicable drug clinical trials, it establishes a clear timeline between the submission of clinical trial registration information and its posting.

Two additional issues directly related to posting of registration information are briefly described further: (1) The administrative data elements that the Agency does not intend to post publicly and (2) the relationship of posting and quality control described in Section IV.D.3 of this preamble. First, section 402(j)(2)(A)(ii)(IV) of the PHS Act specifies that the Secretary "may make publicly available as necessary" administrative data that are submitted as part of clinical trial registration information. We interpret this provision to permit the Secretary to not post certain administrative data in the data bank if the data are not considered necessary for understanding the clinical trial or for recruitment. As noted for each data element discussed in Section IV.B.4 of this preamble, we do not believe it is necessary to make public the following administrative data and currently do not intend to post them publicly in *ClinicalTrials.gov* for any applicable clinical trials: (1) Food and Drug Administration IND or IDE Number and (2) Responsible Party Contact Information other than the name of the responsible party if the responsible party is an individual (as opposed to an entity). Second, as described in further detail in Section IV.D.3 of this preamble, we intend to continue a form of quality control review at the time of clinical trial information submission that is similar to the procedures we have been using for the past several years. We note here, however, that, because the quality control review process does not affect the statutory deadlines for submitting or publicly posting submitted clinical trial information, there will be cases in which submitted clinical trial information is posted even though the quality control review process has not concluded. Although we will post clinical trial registration information not later than 30 calendar days after submission, we will not assign an NCT number until the quality control review process has concluded. Thus, the clinical trial registration information will be posted to the *ClinicalTrials.gov* Web site without an NCT number. In addition, the clinical trial record will contain information that will be visible to those viewing the record on *ClinicalTrials.gov* to make it clear that the quality control review process has not concluded for the posted registration information.

Reflecting section 402(j)(2)(C) of the PHS Act, as codified in § 11.22, the timelines in § 11.35 apply only to clinical trials that are required to register with *ClinicalTrials.gov*. If a clinical trial is registered with *ClinicalTrials.gov* as a voluntary submission as specified in § 11.60, the registration information will be posted as soon as practicable after it has been submitted and reviewed as part of quality control review procedures.

C. Subpart C—Results Information Submission

Subpart C sets forth requirements and procedures related to the submission of results information. In addressing what constitutes results information, subpart C does not specify what results information must be collected while the applicable clinical trial or other clinical trial is being conducted, but rather spells out which elements of the collected data must be submitted and in what required format. Subpart C also specifies when NIH will post results information in *ClinicalTrials.gov* and what procedures may be used to request a waiver of any applicable requirements for results information submission. Below, we summarize each section of subpart C, summarizing its statutory basis, what we proposed in the NPRM, any public comments received on the proposal, and the approach we take in the final rule.

1. § 11.40—Who must submit clinical trial results information?

Overview of Proposal

Proposed § 11.40 required that the responsible party for an applicable clinical trial specified in proposed § 11.42 submit clinical trial results information for that clinical trial. This approach is consistent with section 402(j)(3)(E)(i) of the PHS Act (79 FR 69632).

Comments and Response

No comments were received on this section.

Final Rule

The final rule maintains § 11.40 as proposed.

2. § 11.42—For which applicable clinical trials must clinical trial results information be submitted?

Overview of Proposal

In the NPRM, § 11.42 detailed the applicable clinical trials for which results information would be required to be submitted in accordance with subpart C to *ClinicalTrials.gov,* unless the requirement is waived under proposed § 11.54 (79 FR 69632). Pursuant to section 402(j)(3)(D)(ii)(I) of the PHS Act, § 11.42 proposed to require the submission of results information for specified: (1) Applicable clinical trials of drugs that are approved under section 505 of the FD&C Act or licensed under section 351 of the PHS Act; and (2) applicable clinical trials of devices that are cleared under section 510(k) of the FD&C Act or approved under section 515 or 520(m) of the FD&C Act. Proposed § 11.42 also would have required the submission of results information for specified applicable clinical trials of drugs or devices that are not approved, licensed, or cleared for any indication (regardless of whether the sponsor seeks approval, licensure, or clearance). We noted that proposed § 11.42 pertains to section 402(j)(3)(D)(ii)(II) of the PHS Act, which directs that the Secretary establish through regulation whether or not results information must be submitted for applicable clinical trials of drugs and devices that have not been approved, licensed, or cleared by FDA, whether or not approval, licensure, or clearance is sought (79 FR 69632).

In the NPRM, § 11.42 proposed to require responsible parties to submit results information for applicable clinical trials that are required to be registered with *ClinicalTrials.gov* under § 11.22 and that met one of the following criteria: (a) The completion date is on or after the rule's effective date (§ 11.42(a)); or (b) the completion date is prior to the effective date of this rule, the applicable deadline established by § 11.44 is on or after the effective date of the rule, and clinical trial results information is submitted on or after the effective date of the rule, consistent with the applicable deadline established by § 11.44 (§ 11.42(b)) (79 FR 69632). The NPRM also stated in the discussion of the effective date/compliance date (Section III.D) that for results information due prior to the rule's effective date under section 402(j)(3)(C) of the PHS Act, if the responsible party did not in fact submit these results by the effective date, then the responsible party would be required to submit the clinical trial results information specified by § 11.48 (79 FR 69593).

In addition, the NPRM proposed how the rule would handle an applicable clinical trial of a drug or device under study that was not approved, licensed, or cleared by FDA and reached its completion date prior to the effective date of the rule, but the product is subsequently approved, licensed, or cleared by FDA after the effective date. We proposed that responsible parties for such applicable clinical trials be required to submit clinical trial results information specified in § 11.48 by the earlier of 1 year after the completion date or 30 calendar days after the date of initial FDA approval, licensure, or clearance (79 FR 69594).

Comments and Response

We received a few comments on the issues specifically covered by proposed § 11.42. Those commenters suggested that results information submission should not be required for trials with results published in a peer-reviewed journal and that a hyperlink from *ClinicalTrials.gov* to the published study and lay summary of results would suffice. While results information submission to *ClinicalTrials.gov* is required by section 402(j) of the PHS Act independently of publication, *ClinicalTrials.gov* currently provides a number of optional data elements such as Citations and Links, which can be used to link a record to relevant trial results cited in publications or available at another Web site, respectively [Ref. 97]. We anticipate that these optional data elements will continue to be available on *ClinicalTrials.gov*.

We also received comments on issues relevant to proposed § 11.42. Several commenters suggested that the rule should require results information for applicable clinical trials completed at any time, in order to ensure public access to such results information for completed trials of drugs that are currently on the market. Applicable clinical trials initiated on or before September 27, 2007, or completed before December 26, 2007, are not required to register or submit results information under section 402(j) of the PHS Act. As discussed here and furthermore in Section III.B Submission of Results Information for Applicable Clinical Trials of Unapproved, Unlicensed, or Uncleared Products for Any Use and Section IV.F Effective Date, Compliance Date, and Applicability of Requirements in this Part in the preamble, in the final rule, the NIH requires results information submission from applicable clinical trials of products that were unapproved, unlicensed, or uncleared before the primary completion date but subsequently approved, licensed, or cleared after the primary completion date when the primary completion date is on or after the effective date of the final rule. That is, with this rule, we require results information from trials completed after the effective date, regardless of whether approval, licensure, or clearance of the studied product is sought. A related suggestion in comments was to require submission of results information from applicable clinical trials completed since the year 2000. The submission of results information pursuant to these regulations, from trials with a primary completion date before the effective date of the regulations, is not required. Submission of basic results information (as defined in 402(j)(3)(C) of the PHS Act) from applicable clinical trials has been a statutory requirement since September 27, 2008, however, and is required for applicable clinical trials with a primary completion date before the effective date of the final rule.

Finally, some commenters opposed the NPRM requirement that responsible parties who previously submitted results information for outcome measures would be required to comply with the final rule, anissue discussed in more depth in Section IV.F. of the preamble, Effective Date, Compliance Date, and Applicability of Requirements in this Part. As discussed in Section IV.F., the results information submission requirements that apply to an applicable clinical trial are determined by the date on which the trial reaches its actual primary completion date rather than when a responsible party submits results information.

Final Rule

Taking into consideration these submitted comments as well as the statutory requirements, we have modified § 11.42 in the final rule. We clarify which applicable clinical trials must submit results information according to the final rule and, consistent with the discussion in Section IV.F. of the preamble, we have made revisions and have restructured § 11.42 to address the differing requirements that apply to applicable clinical trials (and, if voluntarily submitted, other clinical trials). Section 11.42(a) applies to applicable clinical trials for which the studied product is approved, licensed, or cleared by FDA. If the primary completion date for such trial is before the effective date of the final rule, § 11.42(a)(1) requires clinical trial results information submission as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act. If the primary completion date for such trial is on or after the effective date of the final rule, § 11.42(a)(2) requires clinical trial results information submission as specified in § 11.48. As discussed further in Section IV.F. on Effective Date, Compliance Date, and Applicability of Requirements in this Part, results information submission requirements are determined by the date on which the trial reaches its actual primary completion date. Thus, for trials that reach their primary completion date before the effective date of the final rule, results information submission is required as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act, and for trials that reach their primary completion date on or after the effective date of the final rule, results information submission is required as specified in this final rule.

Section 11.42(b) applies to applicable clinical trials for which the studied product is not approved, licensed, or cleared by FDA. As discussed in Section III.B Submission of Results Information for Applicable Clinical Trials of Unapproved, Unlicensed, or Uncleared Products for Any Use and Section IV.E. Effective Date, Compliance Date, and Applicability of Requirements in this Part, such applicable clinical trials are not subject to results information submission requirements until the effective date of the final rule. Thus, § 11.42(b) only applies to applicable clinical trials for which the studied product is not approved, licensed, or cleared if those trials have a primary completion date on or after the effective date of the final rule. For such trials, clinical trial results information is required to be submitted as specified in § 11.48.

We note that proposed § 11.42(b) had outlined scenarios in which the completion date of the trial is prior to the effective date of the rule and results information was required to be submitted according to the proposed rule. Under the simplified approach taken in the final rule, as discussed in Section IV.F., because determination of results information submission requirements relies on the primary completion date in relation to the effective date, proposed § 11.42(b) is no longer necessary. That is, there will be no scenarios in which the primary completion date is prior to the effective date of the rule and results information is required to be submitted according to the rule. We also note that the requirement to submit results information for applicable clinical trials with a primary completion date that is on or after the effective date, as specified in § 11.48, applies regardless of whether any results information, including for primary outcome measure(s), has been submitted before the effective date.

3. § 11.44—When must results information be submitted for applicable clinical trials subject to § 11.42?

Overview of Proposal

Proposed § 11.44 specified the deadlines for submitting results information for applicable clinical trials, implementing section 402(j)(3)(E) of the PHS Act. Proposed § 11.44(a) specified the standard submission deadlines for applicable clinical trials that are clinical trials subject to proposed § 11.42. Proposed § 11.44(b) and (c) described procedures for delaying the standard submission deadlines with certification when seeking approval, licensure, or clearance of a new use or initial approval, licensure, or clearance, respectively, of a drug (including a biological product) or device studied in an applicable clinical trial. Proposed § 11.44(d) specified the procedures for submitting partial results information, while § 11.44(e) described the process for requesting an extension of the results information submission deadline for good cause. Finally, proposed § 11.44(f) established the timeline for submitting results of a pediatric postmarket surveillance of a device that is not a clinical trial (79 FR 69632). Below we discuss each part of § 11.44 separately.

§ 11.44(a) Standard Submission Deadline

Overview of Proposal

Proposed § 11.44(a)(1) specified that, in general, the deadline for submitting results information for an applicable clinical trial would be 1 year after the completion date of the clinical trial. As explained in the NPRM, sections 402(j)(3)(E)(i)(I) and (II) of the PHS Act specify that results information is to be submitted not later than 1 year after the "earlier of" the estimated completion date or the actual completion date (79 FR 69632). Under proposed § 11.64(b)(1), however, responsible parties would be required to update the estimated completion date not later than 30 calendar days after a change to the estimated completion date has occurred or after the applicable clinical trial has reached its actual completion date. Therefore, submission 1 year after the actual completion date would then always reflect the "earlier of" 1 year after the estimated completion date or the actual completion date. Thus, under proposed § 11.44(a)(1), results information would be due not later than 1 year after the actual completion date of the applicable clinical trial. This proposed 1 year standard submission deadline would apply to applicable clinical trials of drugs and devices in order to simplify results information submission procedures and provide consistency between the deadlines for applicable clinical trials, regardless of the approval status of the products under study. Section 402(j)(3)(D)(iv)(III) of the PHS Act requires the Secretary to determine by regulation "the date by which . . . clinical trial [results] information [for applicable clinical trials of unapproved, unlicensed, or uncleared products] shall be required to be submitted . . ." Applicable clinical trials of unapproved, unlicensed, or uncleared drugs and devices, and of approved, licensed, or cleared drugs and devices that are studied for a new use may, however, qualify for delayed submission of results information, as described below. As we noted in the NPRM, although section 402(j)(3)(D)(iv)(I) of the PHS Act requires the Secretary to determine whether to increase the standard submission deadline for results information submission from 1 year to "a period not to exceed 18 months" after the earlier of the estimated or actual primary completion date, the Agency chose not to propose extending the general results information submission deadline to as long as 18 months (79 FR 69633).

Proposed § 11.44(a)(2) specified that the deadline for submitting results information for any applicable clinical trial of an FDA-regulated drug (including a biological product) or device that is unapproved, unlicensed, or uncleared as of its completion date would be by the earlier of 1 year after the completion date, or 30 calendar days after FDA approves, licenses, or clears the drug or device for any indication studied in the applicable clinical trial (79 FR 69633).

Comments and Response

Comments on proposed § 11.44 expressed different opinions. While one commenter expressed overall support for the proposal, others suggested modifications to various parts. Others raised concerns that the overall proposed submission and public posting timelines for trial results information could lead to premature dissemination of confidential commercial information, especially if posted prior to peer-reviewed publication or review by the FDA.

As we explained in the NPRM, we did not propose to require the submission of detailed information about clinical trial results (such as required for inclusion in an NDA submitted to FDA), but only summary results data typically found as tables or figures in journal articles, scientific abstracts, and press releases. As mandated by section 402(j)(3) of the PHS Act and established in the final rule § 11.48, responsible parties are required to submit at minimum a standard set of data elements needed to understand the findings from an applicable clinical trial for all prespecified primary and secondary outcome measures and serious adverse events in a structured manner. Further, results information submissions are required for all applicable clinical trials subject to the final rule according to deadlines established by the final rule, regardless of product approval status, to ensure consistent and timely public access to comprehensive summary results for all relevant clinical trials, thereby mitigating the prevalent problems of selective results reporting and negative results publication bias [Ref. 21, 22].

One commenter suggested that the results information submission time frames prescribed in the final rule should conform to those outlined in the 2015 IOM report on sharing clinical trial data [Ref. 47] to minimize the administrative burden on sponsors and responsible parties. Another commenter suggested that results information should be made available as it is created (*i.e.*, real time submission). The requirements in the final rule are consistent with the Agency's authority in section 402(j) of the PHS Act and represent the Agency's determination, consistent with that authority, as to the appropriate results information submission deadlines for applicable clinical trials of unapproved products.

Regarding the standard results information submission deadline following initial approval, licensure, or clearance, described in proposed § 11.44(a)(2), one commenter recommended that, for applicable clinical trials of unapproved, unlicensed, or uncleared products for which the collection of pre-specified secondary outcome measures continues past the completion date, the standard results information submission deadline should be extended to the date of final data collection for all pre-specified secondary outcome measures (*i.e.*, at LPLV). The commenter also suggested that such a change would be consistent with results information submission deadlines established under the EU's Clinical Trials Regulation [Ref. 70]. Section 402(j)(D)(iv)(I) of the PHS Act authorizes the Agency to increase by regulation the standard results information submission deadline from 1 year following the completion date described in 402(j)(3)(E)(i) of the PHS Act "to a period not to exceed 18 months." The statutorily-mandated definition of completion date (here referred to as primary completion date; see preamble Section IV.A.5 and § 11.10(a)) is determined by the status of data collection for solely the primary outcome measure(s), as is the basis for determining the standard results information submission deadline from the statutorily-mandated primary completion date. The final rule permits the responsible party to delay submission of results information for applicable clinical trials for up to 2 additional years by submitting a certification under § 11.44(b) if the manufacturer is the sponsor and is seeking approval, licensure, or clearance for a new use or under § 11.44(c) if the sponsor is seeking initial approval, licensure, or clearance. Such delays provide up to 2 additional years to complete data collection for pre-specified outcome measures and/or additional adverse event information.

Further, the final rule specifies timelines in § 11.44(d) for submitting partial results information by the date on which results information is due even if data collection for secondary outcome measure(s), or the pre-specified time frame for collecting additional adverse events information, has not been completed. These timelines provide submission deadlines for additional partial results information of not later than 1 year after the date on which final data collection for secondary outcome measure(s) or the pre-specified time frame for collecting additional adverse event information is completed, or on the date on which results information for primary outcome measure(s) is due following delayed certification, as specified in § 11.44(b) and (c). In addition, this approach ensures timely submission of results information for the primary outcome measure(s), but permits delays for the submission of other results information to allow time for the final collection and analysis of secondary outcome measure(s) and/or additional adverse event information. We note that, in situations in which the submission of results information for the primary outcome(s) of an applicable clinical trial would impair or otherwise bias the ongoing collection, analysis, and/or interpretation of data for secondary outcome(s) (*e.g.*, need to maintain masking in a trial), responsible parties may request an extension of the results information submission deadline for good cause by following the procedures specified in § 11.44(e).

A few other commenters suggested modifying proposed § 11.44(a)(2), which addressed results information submission for applicable clinical trials of products not approved, licensed, or cleared as of the completion date, but that receive FDA approval, licensure, or clearance thereafter. These commenters asserted that the proposal is inconsistent with the statutory language. In particular, they asserted the proposed regulatory language stating that results information submission is required "by the earlier of" (i) 1 year after the completion date or (ii) 30 calendar days after FDA approval, licensure, or clearance of the product contradicts section 402(j)(3)(E)(i) of the PHS Act, which states "not later than 1 year, or such other period as may be provided by regulation." The commenters suggested that to be consistent with the statute, the standard results information submission deadline should be changed to "by the later of" in the final rule. As discussed in Section IV.F below, we have reconsidered the approach described in the NPRM (79 FR 69593) with respect to determining whether an applicable trial involves an approved, licensed, or cleared product, or whether it involves an unapproved, unlicensed, or uncleared product. For purposes of this final rule, the marketing status of a product will be determined based on its marketing status on the primary completion date. Thus, if a drug product (including a biological product) or a device product is approved, licensed, or cleared for any use as of the primary completion date, we will consider that applicable clinical trial to be a trial of an approved, licensed, or cleared product. Similarly, if a drug product (including a biological product) or a device product is unapproved, unlicensed, or uncleared for any use as of the primary completion date, regardless of whether it is later approved, licensed, or cleared, we will consider that applicable clinical trial to be a trial of an unapproved, unlicensed, or uncleared product. Furthermore, as noted in the preamble section discussing § 11.42(b) and in Section III.B Submission of Results Information for Applicable Clinical Trials of Unapproved, Unlicensed, or Uncleared Products for Any Use and Section IV.F. Effective Date, Compliance Date, and Applicability of Requirements in this Part, applicable clinical trials of an unapproved, unlicensed, or uncleared product are not subject to results information submission requirements until the effective date of the final rule. Thus, whether results information submission is required for an applicable clinical trial of an unapproved, unlicensed, or uncleared product depends on whether the primary completion date for that trial falls before, on, or after the effective date of the rule. Results information submission, therefore, is not required for applicable clinical trials of products not approved, licensed, or cleared for any use as of the primary completion date but receive FDA approval, licensure, or clearance thereafter when the primary completion date is before the effective date of the rule.

Other commenters suggested that results information submission should be required earlier than the proposed standard submission deadline (*i.e.*, earlier than 1 year after the completion date) whenever a responsible party publicly discloses results information for a clinical trial elsewhere, such as in a publication. Some commenters also suggested that the deadline for submission of results information in this circumstance should be 30 days after the date of public disclosure.

The Agency disagrees with the suggestion that we should make the date of any public disclosure of trial results a "trigger" for mandatory early results information submission. Sponsors and researchers publicly disclose trial results for many reasons, including compliance with other federal laws or policies (*e.g.*, disclosure requirements to the U.S. Securities and Exchange

Commission that may contain information about trial results). The final rule is consistent with section 402(j)(3)(E)(i) of the PHS Act, which provides up to 1 year from the completion date for results information submission. For the purpose of describing mandatory results information submission deadlines under this section, a triggering event refers to any of the events specified in paragraphs (b)(1)(i), (ii), and (iii) and paragraphs (c)(1)(i) and (ii) of this section that prompt results information submission for a clinical trial with a certification for delayed results information submission. The responsible party has 30 calendar days from the date of a triggering event to submit results information. We note that the definition of "primary completion date" in § 11.10(a) refers to the definition of "completion date" in § 11.10(a), which is "for a clinical trial, including an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. In the case of clinical trials with more than one primary outcome measure with different primary completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes. For a pediatric postmarket surveillance of a device product that is not a clinical trial, completion date means the date on which the final report of the pediatric postmarket surveillance of the device product is submitted to FDA. For purposes of this part, completion date will be referred to as 'primary completion date.' " In the case that data collection is completed for at least one primary outcome measure (but not yet for all primary outcome measures), clinical trial results information as specified in § 11.48(a) may be submitted before the primary completion date of the clinical trial.

Final Rule

Taking into consideration the commenters' suggestions and the statutory requirements for results information submission deadlines, the final rule modifies the approach proposed in § 11.44(a) by deleting proposed § 11.44(a)(2), which would have required results information submission for a clinical trial of a product that is unapproved, unlicensed, or uncleared for any use as of its completion date by the earlier of 1 year after the completion date or 30 calendar days after the date FDA approves, licenses, or clears the drug or device for any indication studied in the applicable clinical trial.

As noted above and discussed in Section IV.F on Effective Date, Compliance Date, and Applicability of Requirements in this Part, the Agency has reconsidered its approach with respect to determining whether an applicable clinical trial involves an approved, licensed, or cleared product, or whether it involves an unapproved, unlicensed, or uncleared product. For purposes of this final rule, the marketing status of a product will be determined based on its marketing status as of the primary completion date. With this approach, under section 402(j)(3)(C) of the PHS Act, results information submission is not required for clinical trials of a product that is unapproved, unlicensed, or uncleared for any indication as of its primary completion date where the primary completion is before the effective date. Further, as discussed in Section III.B Submission of Results Information for Applicable Clinical Trials of Unapproved, Unlicensed, or Uncleared Products for Any Use and Section IV.F Effective Date, Compliance Date, and Applicability of Requirements in this Part of the preamble, when the primary completion date is on or after the effective date of the final rule, the rule requires results information submission from applicable clinical trials of all products that were unapproved, unlicensed, or uncleared for any indication before the primary completion date. For trials of unapproved, unlicensed, or uncleared products completed after the effective date, results submission is generally required in accordance with the standard submission deadline. Thus, it is not necessary for final § 11.44(a) to contain separate subparagraphs to account for the approval, clearance, or licensure status of the product studied by the applicable clinical trial.

Final § 11.44(a) retains the proposed standard submission deadline of 1 year after the primary completion date regardless of product approval, clearance, or licensure status. We clarify that § 11.44(a) applies to applicable clinical trials subject to § 11.42 and that the results information required is specified in either sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act or in § 11.48, as appropriate. As discussed in Section IV.F Effective Date, Compliance Date, and Applicability of Requirements in this Part, below, whether a responsible party is required to submit either results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act or the results information specified in § 11.48 will depend on whether the primary completion date of the applicable clinical trial is before, on, or after the effective date of the final rule.

§ 11.44(b) and (c)—Delayed Submission of Results Information With Certification

Overview of Proposal

Proposed § 11.44(b) and (c) established procedures whereby responsible parties may delay submission of results information for a particular applicable clinical trial beyond the standard submission deadline specified in proposed § 11.44(a)(1) (*i.e.,* 1 year after the completion date) (79 FR 69633).

Delayed Submission of Results Information With Certification If Seeking Approval, Licensure, or Clearance of a New Use

Consistent with sections 402(j)(3)(E)(iii) and (v) of the PHS Act, we proposed in § 11.44(b) to allow a delay in the submission of results information if the responsible party certifies that an applicable clinical trial meets the following criteria: (1) The drug (including biological product) or device studied in the applicable clinical trial previously has been approved, licensed, or cleared by FDA; (2) the sponsor of the applicable clinical trial is the manufacturer of the product; and, (3) the manufacturer has filed, or will file within 1 year, an application or premarket notification seeking approval, licensure, or clearance of the use being studied in the applicable clinical trial (and is not included in the labeling of the approved, licensed, or cleared drug or device). As proposed, the responsible party would need to submit this certification to *ClinicalTrials.gov* before the standard submission deadline specified in proposed § 11.44(a)(1) (*i.e.,* 1 year or less after the completion date). We also proposed to indicate on the posted record for the clinical trial that results submission has been delayed, but would not specify the particular reason for the delay (79 FR 69633).

As we explained in the NPRM, in accordance with section 402(j)(3)(E)(v) of the PHS Act, once a certification has been submitted to *ClinicalTrials.gov,* proposed § 11.44(b)(2) would permit a delay in the submission of results information of up to 2 years after the date on which the certification is submitted, unless one of the following events occurs: (1) FDA approves, licenses, or clears the drug or device for the use studied in the applicable clinical trial; (2) FDA issues a letter that ends the regulatory review cycle for the application or submission (*e.g.*, a complete response letter, a not substantially equivalent letter, or a not approvable letter) but does not approve, license, or clear the drug or device for the use studied in the applicable clinical trial; or, (3) the manufacturer, which is also the sponsor of the applicable clinical trial, withdraws the application or premarket notification seeking approval, licensure, or clearance of the new use and does not resubmit it within 210 calendar days. In the event that any one of these triggering events occurs, the proposed rule said that the responsible party would be required to submit results information for the applicable clinical trial for which a certification had been submitted under proposed § 11.44(b)(1) not later than 30 calendar days after the earliest of the triggering events occurred, consistent with section 402(j)(3)(E)(v)(I) of the PHS Act (79 FR 69633).

As we noted, proposed § 11.44(b)(3) implemented section 402(j)(3)(E)(v)(II) of the PHS Act, which specifies that if a responsible party who is both the manufacturer of the drug or device studied in the applicable clinical trial and the sponsor of the applicable clinical trial submits a certification to delay submission of results information because the manufacturer is seeking or will seek within 1 year approval, licensure, or clearance of a new use for a drug or device, that responsible party must submit such a certification for each applicable clinical trial that meets the following criteria: (i) The applicable clinical trial is required to be submitted in an application or premarket notification for seeking approval, licensure, or clearance of a new use; and, (ii) the applicable clinical trial studies the same drug or device for the same use as studied in the applicable clinical trial for which the initial certification was submitted (79 FR 69633).

Delayed Submission of Results With Certification If Seeking Initial Approval, Licensure, or Clearance

Proposed § 11.44(c) described requirements for delayed submission of results information with certification when seeking initial approval, licensure, or clearance of a drug or device. As we explained in the NPRM, section 402(j)(3)(D)(iv)(III) of the PHS Act required that, when proposing to require the submission of results information for trials of unapproved, unlicensed, or uncleared products, we take into account the certification process in section 402(j)(3)(E)(iii) of the PHS Act "when approval, licensure, or clearance is sought," and that we determine "whether there should be a delay of submission when approval, licensure or clearance will not be sought" (79 FR 69634).

We proposed in § 11.44(c) to allow a delay in the submission of results information if the responsible party certifies that an applicable clinical trial meets the following criteria: (1) The drug (including biological product) or device studied in the applicable clinical trial was not approved, licensed, or cleared by FDA for any use before the completion date of the clinical trial; and, (2) the sponsor of the applicable clinical trial intends to continue with product development and is seeking, or may at a future date seek, FDA approval, licensure, or clearance of the drug or device under study. As proposed, this certification would be required to be submitted to *ClinicalTrials.gov* before the standard submission deadline specified in proposed § 11.44(a)(1) (*i.e.*, 1 year or less after the completion date). The record for the clinical trial would indicate that results submission has been delayed, but would not specify the particular reason for the delay (79 FR 69634).

As proposed in § 11.44(c), submission of a certification would permit a delay in the submission of results information of up to 2 years after the date on which the certification is submitted to *ClinicalTrials.gov*, unless either of the following events occurs: (1) FDA approves, licenses, or clears the drug or device studied in the applicable clinical trial for any indication that is studied in the clinical trial; or, (2) the application or premarket notification is withdrawn without resubmission for not less than 210 calendar days. The responsible party would be required to submit results information not later than 30 calendar days after the one of these triggering events occurs. We explained that the Agency included the second event (*i.e.*, withdrawn without resubmission for not less than 210 calendar days) because we believe that this situation represents a significant enough interruption to product development to trigger the submission of results information. Unlike delayed results information submission with certification under proposed § 11.44(b), which applies when the sponsor (which is the manufacturer) of the applicable clinical trial is seeking approval, licensure, or clearance of a new use, we did not propose to require the submission of results information 30 calendar days after FDA issues a letter not approving, not licensing, or not clearing the product under study for delayed results information submission with certification seeking initial approval, licensure, or clearance because the issuance of such a letter does not necessarily indicate abandonment of product development (79 FR 69634).

Two-Year Limitation of Delay

As we discussed in the NPRM, with regard to the maximum 2-year delay pursuant to a certification submitted under section 402(j)(3)(E)(iii) of the PHS Act, we had considered establishing the maximum available delay with certification when seeking initial approval, licensure, or clearance to be 3 years from the completion date of the applicable clinical trial, regardless of when during the 1-year period following the completion date the certification is submitted. Such a provision would have accomplished the same objective as the statutory provision for delayed submission when seeking approval, licensure, or clearance of a new use by allowing responsible parties to delay results submission by as long as 3 years beyond the completion date of a clinical trial, but without creating a disincentive to submit the certification early. As we explained in the NPRM, measuring the 2-year period from the date on which the certification is submitted may result in responsible parties submitting certifications as close as possible to the standard results submission deadline under proposed § 11.44(a)(1) to obtain the full 3-year delay after the completion date. Section 402(j)(3)(D)(iv)(III) of the PHS Act expressly authorizes the Secretary to establish the date by which clinical trial information for applicable clinical trials of unapproved products must be submitted to *ClinicalTrials.gov*. Thus, in order to maintain the same maximum delay for results information submission whether seeking initial approval, licensure, or clearance or seeking approval, licensure, or clearance of a new use, we did not propose that the maximum 3-year delay apply regardless of when during the 1-year period following the completion date the certification is submitted. We invited public comments on establishing different maximum timelines for results information submission under the two delayed-results-with-certification provisions and on alternative approaches to encourage early submission of certifications that would be consistent with the statute, without causing a responsible party to have to submit results information earlier than the latest deadline they could have under the statute (79 FR 69635).

Explanation of "initial approval," "initial clearance," and "approval of a new use," or clearance of a new use"

For purposes of proposed § 11.44(b) and (c), we interpreted the term "drug" in sections 402(j)(3)(E)(iv) and 402(j)(3)(E)(v) of the PHS Act to mean "drug product" or "biological product," referring to a finished product that is approved or licensed for marketing, and not to the active ingredient or active moiety in such a product. We concluded that this is the most appropriate interpretation of the statutory term and that this interpretation is consistent with the statutory intent to draw a distinction between applicable drug clinical trials that are "completed before the drug is initially approved" (see section 402(j)(3)(E)(iv) of the PHS Act) and those pertaining to uses "not included in the labeling of the approved drug" (see section 402(j)(3)(E)(v) of the PHS Act). Accordingly, we interpreted "initial approval" to pertain to the approval or licensure of an original NDA, ANDA or BLA, and "new use" to pertain to the approval or licensure of a supplemental NDA, ANDA, or BLA for an additional use for that particular drug product or biological product. Similarly, we interpreted "initial approval" of a device under sections 515 or 520(m) of the FD&C Act to pertain to the approval of an original PMA or HDE and "new use" to pertain to the approval of a supplemental PMA for an additional use for that particular device. In addition, for purposes of proposed § 11.44(c), we considered the first 510(k) cleared for a particular device type as the "initial clearance" of the device. Consequently, for purposes of proposed § 11.44(b), all other 510(k)s cleared for a device type, other than the first one, would have been considered "clearance of a new use." We solicited comments on whether these are appropriate interpretations and distinctions for purposes of proposed § 11.44(b) and (c) (79 FR 69635).

Comments and Response

Commenters addressed delayed submission of results with certification in proposed § 11.44(b) and (c). While one commenter supported the proposed delay of results submission for up to 2 years following the date of submission of a certification in proposed § 11.44(c), another commenter proposed simplifying the approach for calculating the deadline for this maximum delay by uniformly allowing up to 3 years after the primary completion date, regardless of when a certification is submitted. This commenter, however, did not explain how the statute allows for this proposed approach. As noted previously here and in the proposed rule, the statute does not permit changing by rulemaking when the 2-year maximum available delay for results submission would begin for submitted certifications seeking approval, licensure, or clearance of a new use for the studied drug or device. Section 402(j)(3)(E)(v)(III) of the PHS Act states that the time period begins on the date that the certification is submitted. While the statute provides greater flexibility for establishing the timelines for certifications seeking initial approval, licensure, or clearance for a studied drug or device, we have decided to keep the same approach for determining the maximum delay under both types of certifications, for reasons discussed in the NPRM. As such, the final rule retains the proposed approach (*i.e.*, "not later than 2 years after the date on which the certification was submitted").

One commenter proposed allowing an additional year to delay the submission of results for purposes of journal publication. Another commenter suggested that the Agency provide a new certification-like mechanism for delaying the submission of results of applicable clinical trials of approved, licensed, or cleared products for up to 2 years (as permitted for unapproved, unlicensed, or uncleared products) to allow academic researchers to prepare for journal publication. Several commenters proposed that the final rule routinely provide delayed submission of results for other reasons, such as publication prior to public posting on *ClinicalTrials.gov*. The statutory provision that pertains to delayed submission of results with certification is in section 402(j)(3)(D)(iv)(III) of the PHS Act, which explicitly directs the Agency to take into account during rulemaking the delayed submission of results with certification provisions when proposing to require the submission of results for applicable clinical trials of unapproved, unlicensed, or uncleared products, whether or not approval, licensure, or clearance is sought. In response to this mandate, the Agency proposed permitting delayed submission of results in proposed § 11.44(c) for applicable clinical trials of unapproved, unlicensed, or uncleared products undergoing product development. However, the NPRM proposed at § 11.44(a) to require the standard submission deadline for trials of unapproved, unlicensed, or uncleared products for which product development has been abandoned (see Section III.B of this preamble).

The Agency does not agree that submission of results information should be delayed for purposes of journal publication. Moreover, we note that the ICMJE clinical trial registration policy recognizes the results reporting obligations under section 402(j) of the PHS Act and states that "the ICMJE will not consider results data posted in the tabular format required by *ClinicalTrials.gov* to be prior publication" [Ref. 98]. Therefore, we do not expect that the requirements of the final rule for submission of results information will interfere with journal publication of articles about applicable clinical trials.

One commenter proposed requiring submission of results information for applicable device clinical trials only after the manufacturer has declared product development to be abandoned. This commenter noted further that receipt of an initial non-approval or not substantially equivalent finding from the FDA does not necessarily indicate that product development has stopped and suggested that the final rule provide for additional delays for results submission until the manufacturer has declared product development to be abandoned. As discussed in more detail in Section III.B of this preamble, the Agency has decided to maintain the requirement of results information submission for applicable clinical trials of drug and device products that are not approved, licensed, or cleared by the FDA for any use, regardless of whether approval, licensure, or clearance is sought. We continue to believe that this approach is consistent with the express statutory purpose of the expanded data bank "[t]o provide more complete results information and to enhance patient access to and understanding of the results of clinical trials" (see section 402(j)(3)(D)(i) of the PHS Act). As discussed previously, § 11.44(c) mitigates concerns about potential competitive harm resulting from disclosure of results information from applicable clinical trials of products that are not approved, licensed, or cleared by delaying the results submission deadline for applicable clinical trials of products that are still under development. Thus, we do not agree with commenters who suggested that results submission for applicable device clinical trials (or for applicable drug clinical trials) should be limited to trials of abandoned products. Consistent with section 402(j)(3)(E)(v)(I)(bb) of the PHS Act, § 11.44(b)(1)(ii) of the final rule provides that the issuance of a letter by the FDA including "a complete response letter, not approving the submission or not clearing the submission, a not approvable letter, or a not substantially equivalent letter for a new use of the drug or device" that ends the regulatory review cycle for the application or submission but does not approve, license, or clear the product for the use studied in the applicable clinical trial, requires the responsible party to submit within 30 calendar days clinical trial results information for an applicable clinical trial, which had previously been subject to delayed submission of results information.

One commenter suggested that confidential commercial or proprietary information should not need to be submitted as part of the certification process. We clarify that to obtain a certification for delayed results information submission, a responsible party will need to indicate that a particular applicable clinical trial meets the requirement for delayed submission with certification in accordance with § 11.44(b) or (c) and provide the name(s) of the drug product(s), biological product(s), or device product(s), to which the certification applies. This information is necessary to demonstrate that the certification requirement has been met. No additional information will be required as part of this process.

One commenter suggested that we should post the reason a responsible party has been granted a certification for delayed results submission or extension. As noted above in the discussions of § 11.44(b) and (c), for applicable clinical trials that have been granted a certification for delayed results information submission or extension, the posted record will indicate only that the results information submission has been delayed but it will not specify the particular reason for the delay.

Finally, a few commenters disagreed with the Agency's interpretation that only the first 510(k) cleared for a particular device type be considered "initial clearance." They asserted that every 510(k) clearance should be considered "initial clearance," which would result in a potentially longer delay in submitting results information, rather than considered clearance of a "new use" because the trigger for submitting results information in proposed § 11.44(b)(1)(ii) is not found in proposed § 11.44(c). The commenters' arguments appear to be rooted in a concern that premature disclosure of clinical trial results information would enable competitors to shorten the time and expense to develop and market a similar device. The commenters' proposal would result in treating all 510(k) clearances as "initial clearance" under section 402(j)(3)(E)(iv) regardless of whether or not the 510(k) submission is an original submission by a manufacturer to obtain initial clearance of a device product as compared with a subsequent application by the same manufacturer to obtain clearance of the same device product for a different use. The Agency disagrees with the commenters' proposal because, by considering every 510(k) clearance to be an "initial clearance" under section 402(j)(3)(E)(iv) of the PHS Act, and considering no 510(k) clearances to be clearance of a "new use" under section 402(j)(3)(E)(v) of the PHS Act, such an interpretation would deprive section 402(j)(3)(E)(v) of the PHS Act of any meaning with respect to 510(k)s. Accordingly, the commenters' approach would contravene the principle of statutory construction that courts should give effect, if possible, to every clause and word of a statute, so as to avoid rendering any statutory language superfluous.

For NDA, ANDA, BLA, and PMA approvals, the NPRM focused on a manufacturer's particular "product" rather than on the "type" when determining whether a trial would be considered seeking "initial approval," as specified in section 402(j)(3)(E)(iv), or "approval of a new use," as specified in section 402(j)(3)(E)(v). In contrast, for 510(k)s, the NPRM focused on the device "type" rather than the device "product" for making such a determination. Under the NPRM, only the first 510(k) cleared for a device type was considered "initial clearance" and all other 510(k)s cleared for a device type were considered "clearance of a new use." As a result, the NPRM approach resulted in disparate treatment of 510(k)s compared with the treatment of all other types of applications, including device PMAs.

To avoid disparate treatment of 510(k) submissions as compared with the treatment of all other types of applications, including PMA applications, in the final rule, the Agency is focusing on the device "product" rather than the device "type" when determining which 510(k) clearances are considered "initial clearance" versus "clearance of a new use." That is, in the final rule, we interpret "initial clearance" to pertain to the clearance of a manufacturer's original 510(k) submission for a particular device product whereas "clearance of a new use" of a device pertains to the clearance of the same manufacturer's subsequent 510(k) submission for an additional use for the same device product. "Manufacturer" means a manufacturer who is the sponsor for the applicable clinical trial. The final rule, thus, treats 510(k)s in the same way it treats NDAs, ANDAs, BLAs, and PMAs by consistently basing its determination on the "product" rather than the "type" when determining whether a trial is seeking "initial" approval, licensure, or clearance, or approval, licensure, or clearance of a "new use." This represents a middle-ground approach between the NPRM approach and the approach advocated by the commenters.

For the purposes of this final rule only, we interpret "use" to include "indication." For the purposes of this final rule, "indication" means "the disease or condition the product is intended to diagnose, treat, prevent, cure, or mitigate."

Thus, for purposes of the final rule, the Agency interprets the first 510(k) clearance of a device "product" rather than the first 510(k) clearance of a device "type" as "initial clearance" under section 402(j)(3)(E)(iv) of the PHS Act. Any subsequent clearance of an "initially cleared" 510(k) device product for a different use will be considered a "clearance of a new use" under section 402(j)(3)(E)(v) of the PHS Act.

This interpretation in the final rule allows a responsible party for an applicable clinical trial of a 510(k) device product that is uncleared on the primary completion date to seek delayed submission of results information by submitting a certification that it is seeking "initial clearance" of its device product under § 11.44(c), rather than "clearance of a new use" under final § 11.44(b). With regard to FDA's issuance of a letter that ends the regulatory review cycle but does not approve, license, or clear the product for the use studied in the applicable clinical trial, as described in § 11.44(b)(1)(ii), we note, first, that it does *not* trigger results information submission within 30 calendar days of the event under § 11.44(c)(1) and, second, that there are *no* "additional requirements" in § 11.44(c) for responsible parties who are both the manufacturer of the product and the sponsor of the applicable clinical trial to submit certifications for each additional applicable clinical trial that studies the same product for the same use and is required to be submitted in a premarket notification for that use (as required in § 11.44(b)(3)).

We also note that this interpretation has implications for the registration requirements in the final rule because the concepts of "initial clearance" and "clearance of a new use" also appear in the registration provisions of the statute. This interpretation subjects clinical trial registration information for more applicable clinical trials of unapproved or uncleared devices to delayed posting under section 402(j)(2)(D)(ii)(I) as compared with the NPRM approach because each individual device manufacturer seeking initial clearance of its device product would be subject to delayed posting of its clinical trial registration information, as specified in final § 11.35(b)(2)(i), rather than only the first manufacturer to obtain clearance for the device type. We note, however, that under final § 11.35(b)(2)(ii), a responsible party for an applicable device clinical trial that is initiated on or after the effective date of the rule may choose to indicate to the Director that it is authorizing the Director to publicly post its clinical trial registration information, that would otherwise be subject to delayed posting, as specified in § 11.35(b)(2)(i), prior to the date of FDA approval or clearance of the device product.

Final Rule

Final § 11.44(b)(1) retains the proposed procedure to allow a responsible party to delay results information submission with a certification indicating that the manufacturer, who is also the sponsor of the applicable clinical trial, is or will be seeking approval, licensure, or clearance of a new use for the studied drug product (including biological product) or device product, but clarifies that "drug" means "drug product" and "device" means "device product." To obtain such a delay, the responsible party would need to submit a certification to *ClinicalTrials.gov* before the standard submission deadline specified in § 11.44(a) (*i.e.,* 1 year or less after the primary completion date). The responsible party would need to certify that (1) an applicable clinical trial involves an FDA-regulated drug product (including biological product) or device product that previously has been approved, licensed, or cleared by the FDA; (2) for which the manufacturer is the sponsor of the applicable clinical trial; and, (3) for which an application or premarket notification seeking FDA approval, licensure, or clearance of the use being studied in the applicable clinical trial, which is not included in the labeling of the approved, licensed, or cleared drug product (including a biological product) or device product, has been filed or will be filed within 1 year with FDA. The posted record for the applicable clinical trial would indicate that results information submission has been delayed, but would not specify the particular reason for the delay. For purposes of this part, we interpret "manufacturer" to mean a manufacturer who is the sponsor of the applicable clinical trial. Note that if the manufacturer designates a principal investigator as the responsible party as provided for at § 11.4(c)(2), the designated principal investigator would be required to submit the certification for delayed submission of clinical trial results information.

The deadline for the delayed submission of results information under § 11.44(b) would be 30 calendar days after the earliest of: (1) FDA approval, licensure, or clearance of the drug product (including a biological product) or device product for the use studied in the applicable clinical trial; (2) FDA issuance of a letter ending the regulatory review cycle for the application or submission without product approval, licensure, or clearance for the use studied in the applicable clinical trial (*e.g.,* a complete response letter, a not substantially equivalent letter, or a not approvable letter); or, (3) withdrawal of the application or premarket notification without resubmission within 210 calendar days (*i.e.,* 240 calendar days after submission of the withdrawal request). Final § 11.44(b)(2) provides a maximum deadline for delayed results information submission of 2 years after the date of submission of the certification, except to the extent that § 11.44(d) applies. Final § 11.44(b)(3) provides an additional requirement that any responsible party who is both the manufacturer of the drug product (including a biological product) or device product studied and the sponsor of an applicable clinical trial, and who submits a certification for the delayed submission of results under § 11.44(b)(1) for that applicable clinical trial, must also submit such a certification for each applicable clinical trial for which the manufacturer of the drug product (including a biological product) or device product studied is the sponsor and which is required to be submitted in an application or premarket notification seeking approval, licensure, or clearance of a new use studied in the clinical trial.

We note that if the sponsor of an applicable clinical trial for which a "new use certification" has been submitted is also the manufacturer the drug product (including a biological product) or device product studied in the applicable clinical trial, but has designated the principal investigator as the responsible party, then the manufacturer may need to notify the responsible party of the occurrence of a triggering event in order to help ensure that the responsible party is aware of the results information submission deadline. As discussed in § 11.4(c)(2)(i) (see Section IV.A.2 of this preamble), the sponsor may designate a principal investigator as the responsible party only if, among other things, the principal investigator "[h]as the ability to meet all of the requirements for submitting and updating clinical trial information as specified in this part." Accordingly, a responsible party who is not the manufacturer of the drug product (including a biological product) or device product studied will only be able to comply with the results information submission requirements subsequent to a certification under sections 402(j)(3)(E)(iii) and (v) if notified by the manufacturer when one of these triggering events occurs. If a manufacturer is not willing or able to provide the principal investigator with this information, the conditions for designation under § 11.4(c)(2) cannot be met and the manufacturer would become the responsible party until the manufacturer assigns a new responsible party (see § 11.4(c)(3)).

We also note that the maximum delay of 2 years specified in § 11.44(b)(2) would apply to clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act or § 11.48, as applicable. With respect to applicable clinical trials for which data collection for any secondary outcome measures and/or additional adverse event information extends beyond the primary completion date, the deadlines for submission of these clinical trial results information are discussed under final § 11.44(d).

We recognize that in some cases a responsible party may not know whether a particular applicable clinical trial will be used to support an original NDA, ANDA, BLA, PMA, or HDE for initial approval or licensure of a product as opposed to a supplemental NDA, ANDA, BLA, or PMA for approval or licensure of a new use. Similarly, a responsible party may not know whether a clinical trial will be used to support a 510(k) seeking "initial clearance" of a device product as opposed to a 510(k) seeking "clearance of a new use." Responsible parties should use their best judgment based on information available at the time of certification in order to determine whether certification under § 11.44(c) (initial approval, licensure, or clearance) or § 11.44(b) (approval, licensure, or clearance of a new use) is appropriate.

As discussed above, the Agency interprets "initial clearance" in the final rule to apply to the clearance of a manufacturer's original 510(k) submission for a device product for purposes of this part and any subsequent clearance of that device product by that manufacturer for a different use would be considered "clearance of a new use." By making this change, the final rule focuses on the device product, rather than the device type, to determine whether an applicable clinical trial of a 510(k) device will be considered as seeking "initial clearance" versus "clearance of a new use." This means that under the final rule, 510(k) device product trials will be considered not by whether the type of device has ever been cleared before, but by whether the particular manufacturer's device product has ever been cleared.

Final § 11.44(c)(1) retains the proposed procedure to allow a responsible party to delay results information submission with a certification indicating that the sponsor is seeking initial approval, licensure, or clearance for the drug product (including a biological product) or device product, but clarifies that "drug" means "drug product" and "device" means "device product." To obtain such a delay, the responsible party will need to submit a certification to *ClinicalTrials.gov* before the standard deadline specified in proposed § 11.44(a) (*i.e.,* 1 year or less after the primary completion date). The responsible party would need to certify that an applicable clinical trial (1) studies a drug product (including a biological product) or device product that was not approved, licensed, or cleared by FDA for any use before the primary completion date of the clinical trial; and, (2) the sponsor of the applicable clinical trial intends to continue product development and is seeking or intends to seek FDA approval, licensure, or clearance of the drug product (including a biological product) or device product under study. Certifications cannot be submitted for applicable clinical trials of products that the sponsor has no intention of marketing or for which product development has been abandoned.

When a certification for delay is submitted, the posted record for the clinical trial will indicate that results information submission has been delayed, but will not specify the particular reason for the delay. The deadline for delayed submission of results information under § 11.44(c) will be 30 calendar days after the earlier of: (1) FDA approval, licensure, or clearance of the drug product (including a biological product) or device product for the use studied in the applicable clinical trial; or, (2) withdrawal of the application or premarket notification by the sponsor of the applicable clinical trial without resubmission within 210 calendar days (*i.e.,* 240 calendar days after submission of the withdrawal request). We believe that this latter situation represents a significant enough interruption to product development to trigger the submission of results information. Final § 11.44(c)(2) retains a maximum deadline for delayed results information submission of 2 years after the date of certification submission. The Agency expects that a delay of an additional 2 years beyond the date the certification is submitted (*i.e.,* up to 3 years after the primary completion date of the clinical trial, assuming that the certification is submitted 1 year after the primary completion date) is sufficient to address any confidentiality concerns that may be expressed by responsible parties. This time frame allows a sponsor or manufacturer to decide whether to initiate another clinical trial or submit a marketing application or premarket notification to the FDA. A subsequent pre-market clinical trial of a drug product (including a biological product) would likely be an applicable clinical trial that would be registered at *ClinicalTrials.gov,* making public information about the sponsor's intention to pursue product development. Thus, the total delay in disclosure of results information of up to 3 years after the completion date of the trial would provide sponsors with significant lead time in product development over potential competitors. As discussed further in Section III.B of this preamble, we conclude that any competitive disadvantage that may be caused by the disclosure of summary results information for clinical trials of products that have not been approved, licensed, or cleared for any use 3 years or more after the primary completion date of the trial is limited and, in any case, outweighed by the public health benefits of making such information publicly available. Furthermore, as discussed above, even if such summary results information were to contain trade secret and/or confidential commercial information, the requirement that such information be posted on *ClinicalTrials.gov* is authorized by law for the purposes of the U.S. TSA.

Section 11.44(c) permits delayed submission of results information only if the responsible party certifies that the sponsor of the applicable clinical trial is continuing to study the product with an expectation of seeking future initial approval, licensure, or clearance. While we recognize it may be difficult for the sponsor of the applicable clinical trial to know early on in the product development process whether it will seek future initial approval, licensure, or clearance for a product studied in an applicable clinical trial, we would, in general, view further development of a product through subsequent clinical trials as an indication that the product development process is continuing and may lead to seeking initial approval, licensure, or clearance. A responsible party who is not the sponsor of the applicable clinical trial cannot submit a certification to delay results information submission unless the responsible party can obtain such information from the sponsor. If a principal investigator who has been designated as the responsible party by the sponsor cannot obtain such information, then the conditions for designation under § 11.4(c)(2) cannot be met and the responsible party will not be able to submit a certification for delayed results information submission. If a triggering event occurs, the responsible party who is not the sponsor (*i.e.,* a responsible party who is a principal investigator) will only be able to comply with the results information submission requirements under § 11.44(c)(2) if notified by the sponsor. In a situation in which the sponsor is not willing or able to provide the principal investigator with this information, the conditions for designation under § 11.4(c)(2) cannot be met and the responsible party will not be able to submit a certification for delayed results information submission.

As discussed with respect to § 11.44(b)(2), the maximum delay of 2 years specified in § 11.44(c)(2) would apply to clinical trial results information specified in § 11.48. In the event that data collection for any secondary outcome measure(s) will not be completed as of the primary completion date of the trial or the time frame for additional adverse event collection extends beyond the primary completion date, clinical trial results information for such secondary outcome measure(s) and additional adverse events information shall be due by the later of (1) the deadline for delayed submission of results with certification established by either final § 11.44(b) or (c) or (2) the submitting partial results deadlines established in final § 11.44(d)(1).

We also note that after a certification for delayed results information submission has been submitted under either § 11.44(b) or (c) for an applicable clinical trial, the final rule does not permit submission of an additional certification under § 11.44(b) to extend the results information submission deadline established by the existing certification for the same trial (see

§ 11.44(c)(2)). For example, a responsible party who has submitted a certification seeking "initial approval" under § 11.44(c) must submit results information by the earlier of 30 calendar days of the first triggering regulatory event (§ 11.44(c)(1)) or 2 years after the date of certification (§ 11.44(c)(2)), and cannot submit a certification seeking "approval of a new use" for that same trial, even if it studied both uses. Similarly, a responsible party who has submitted a certification seeking approval of a "new use" under § 11.44(b) must submit results information by the earlier of 30 calendar days of the first event described (§ 11.44(b)(1)) or 2 years after the date of certification (§ 11.44(b)(2)), and cannot submit another certification seeking approval of a "new use" for the same trial. We note that in certain situations, as discussed below in this section of the preamble, a responsible party may be able to request an extension for good cause under § 11.44(e).

§ 11.44(d)—Submitting Partial Results Information

Overview of Proposal

Proposed § 11.44(d) specified procedures for submitting results information when required results information, as specified in proposed § 11.48, has not been collected for all secondary outcome measures by the date on which results information is due. Since the definition of completion date in proposed § 11.10(a) is determined by the status of data collection solely for the primary outcome measure(s), an applicable clinical trial may therefore still be collecting data for the secondary outcome measure(s) after it has reached its completion date. In this situation, the responsible party would be required to submit results information for the primary outcome measure(s) by the required due date specified in proposed § 11.44(a), (b), or (c), as applicable. Under proposed § 11.44(d)(1)(i), if a certification to delay results information submission had not been submitted under proposed § 11.44(b) or (c), results information for each remaining secondary outcome measure would be due not later than 1 year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for that secondary outcome measure, whether the clinical trial was concluded according to the pre-specified protocol or was terminated. If the responsible party had submitted a certification to delay results information submission, results information for the secondary outcome measures could be submitted by the later of the date specified in proposed § 11.44(d)(1)(i) or the date on which the primary outcome measure(s) would be required to be submitted under proposed § 11.44(b) or (c) as specified in proposed § 11.44(d)(1)(ii). We noted that in either situation, if data collection for a secondary outcome measure is completed as of the completion date, results information for that secondary outcome measure would be required to be submitted on the same date as results information for the primary outcome measure(s) (79 FR 69635).

We also clarified in proposed § 11.44(d)(2) the process to handle results information submission if results information related to the primary outcome(s) was submitted prior to the effective date of the final rule, but results information for the secondary outcome(s) is required to be submitted after the effective date. In such cases, the responsible party would be required to provide results information for all primary and secondary outcome(s) as specified in § 11.48 of the proposed rule. We indicated that, because we believe consistent data must be provided for all outcome measures in a single clinical trial, the requirements of proposed § 11.48 would apply to all clinical trial results information submitted for a trial (79 FR 69636).

With respect to adverse event information, considered to be part of clinical trial results information described under proposed § 11.48, a responsible party would be required to submit information summarizing serious and frequent adverse events recorded to-date each time results information for a secondary outcome is submitted until all the adverse event information required by this part has been submitted. We indicated that we believe such an approach would provide a better mechanism for handling submission of adverse event information than extending the general results submission deadline for all applicable clinical trials up to 18 months after the completion date. It would ensure that key results information for primary outcome measures is submitted to *ClinicalTrials.gov* within 1 year of the completion date, while allowing subsequent data collection to continue as planned (79 FR 69636).

Comments and Response

Commenters addressed § 11.44(d). One commenter suggested that the final rule require the submission of data for additional adverse event information on an annual basis, rather than during each deadline for the submission of partial results information involving secondary outcomes for which data collection was incomplete by the completion date. The Agency believes that requiring additional adverse event information data to be submitted annually rather than by the proposed partial results deadlines would potentially be more burdensome for responsible parties with few benefits for the public. For example, if a study protocol pre-specified time frames for both a secondary outcome measure and adverse events collection 5 years after the completion date, under the approach proposed in § 11.44(d), the responsible party would only need to submit results information once for the secondary outcome measure as well as data for additional adverse event information not later than 1 year after the date of final data collection (*i.e.,* up to 6 years after the completion date). Under the approach proposed by the commenter, however, that responsible party would also need to submit four datasets of additional adverse event information for this trial, once per year after the completion date until submission of results for the secondary outcome measure. In addition, protocols might not pre-specify that data for adverse event information will be analyzed annually, placing additional burden on the responsible party to prepare adverse event information for submission to the data bank. Thus, the Agency retains the proposed approach with respect to submission of adverse event information each time results information for a secondary outcome is submitted and extends the requirement until all additional adverse event information collected in accordance with the time frame for collecting adverse events pre-specified in the protocol are submitted, even after submission of data for all secondary outcomes.

Reporting of adverse event information is required as part of § 11.48(a)(4), yet the time frame for reporting of partial adverse event information was not specified in proposed § 11.44(d). After reviewing proposed § 11.44(d) in response to this comment, we identified the need to specify explicitly the deadline for submitting partial results information when the pre-specified time frame for collecting data for additional adverse event information is not completed by the primary completion date. We clarify that the final rule addresses this situation by specifying that a responsible party submitting partial results information under § 11.44(d) must submit additional adverse event information by the later of either 1 year after the date of data collection for additional adverse event information or the date on which results information for the primary outcome measures is due if a certification to delay results information submission has been submitted under § 11.44(b) or (c). Further, we have added the Study Completion Date data element, defined in final § 11.10 and discussed in Section IV.A.5 of this preamble, to clinical trial registration information specified in § 11.28.

The Study Completion Date is needed to assist responsible parties and viewers of the posted record to help identify when the final rule requirements for results information submission and obligations for updates and corrections in § 11.64 are fulfilled. Note that even though a responsible party for a trial may need to submit partial results information several times in order to meet different deadlines (*i.e.,* because of different dates for final data collection for primary and/or secondary outcome measures or for the pre-specified time frame for collecting adverse events), that responsible party's obligation under subpart C continues until all required results information is submitted not later than 1 year following the Study Completion Date.

Several additional commenters opposed proposed § 11.44(d)(2), which required that results for primary and secondary outcomes submitted prior to the effective date of the final rule be resubmitted in accordance with final § 11.48 by the deadline for reporting partial results information for secondary outcome measures specified in proposed § 11.44(d)(1). The Agency agrees with these comments. The final rule specifies that if any results information is submitted for a clinical trial under sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act prior to the effective date, those results do *not* need to be resubmitted in accordance with final § 11.48. In addition, partial results submitted for that trial after the effective date are also not subject to § 11.48 of the final rule, but are subject to the results data elements established by sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act, in order to ensure that results data are displayed in a consistent format on the posted record.

Final Rule

The final rule substantively revises the proposed approach to § 11.44(d) in three ways. First, final § 11.44(d)(1)(ii) adds a partial results information submission deadline when adverse event information required in § 11.48(a)(4) has not been collected by the primary completion date. Under the final rule, data collected for additional adverse event information after the primary completion date through the pre-specified adverse event collection time frame must be submitted by the later of 1 year after the date of data collection for additional adverse event information or the date on which results information is due if a certification to delay results information submission has been submitted under § 11.44(b) or (c). Second, the final rule modifies § 11.44(d)(2) to specify that, if any partial results information for a clinical trial is submitted prior to the effective date of the final rule, any remaining results information required to be submitted for that trial after the effective date will be subject to the results requirements established by sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act [42 U.S.C. 282(j)(3)(C) and 282(j)(3)(I)], not by the final rule (§ 11.48). Third, the final rule adds § 11.44(d)(3) to require (i) the submission of a copy of any revised protocol and/or statistical analysis plan, as described in § 11.48(a)(5), if any amendments were made to the protocol and/or statistical analysis plan since the previous submission of partial results information and (ii) the submission of results information about certain agreements between the principal investigator and the sponsor as described in § 11.48(a)(6)(ii) if that information has changed since the previous submission of partial results information.

Final § 11.44(d)(1) describes the partial results information submission deadlines when all clinical trial results information required in § 11.48 has not been collected by the primary completion date. In such cases, results information for secondary outcome measures must be submitted by the later of 1 year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for that secondary outcome measure or the date on which results information is due if a certification to delay results information submission has been submitted under § 11.44(b) or (c). Furthermore, as discussed above, data collected for additional adverse event information after the primary completion date through the pre-specified adverse event collection time frame must be submitted by the later of 1 year after the date of data collection for additional adverse event information or the date on which results information is due if a certification to delay results information submission has been submitted under § 11.44(b) or (c).

We clarify that when submitting partial results information (pending completion of data collection for secondary outcomes and/or the pre-specified time frame for collecting additional adverse event information), the responsible party is required to submit the clinical trial results information as specified in § 11.48 that is otherwise available when submitting partial results information. This means that, with respect to adverse event information (considered to be part of clinical trial results information described under § 11.48), each time results information for a secondary outcome is submitted, a responsible party would be required to submit results information summarizing serious and frequent adverse events and all-cause mortality recorded to that date until all the adverse event information required by this part has been submitted. If adverse event information was not planned to be collected and reported in the same time frame(s) as secondary outcome measures, then it does not need to be reported each time information for a secondary outcome measure(s) is submitted. However, as specified in § 11.48(a)(4)(i)(A), the Time Frame must clearly indicate the time period over which adverse information is reported and describe any additional time periods over which adverse event information will be submitted, as pre-specified. It is important to reiterate that this provision would not impose requirements on the design or conduct of the clinical trial or on the data that must be collected during the clinical trial.

Final § 11.44(d)(2) specifies that if any results information is submitted for a clinical trial under sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act prior to the effective date, the responsible party is not required to resubmit those results in accordance with § 11.48. In addition, subsequent partial results information as specified in § 11.44(d)(1) submitted for the same trial after the effective date is also not required to be submitted in accordance with final § 11.48, but in accordance with the results data elements established by sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act. Final § 11.44(d)(3)(i) specifies that the responsible party is required to also submit a copy of the revised protocol and/or statistical analysis plan when submitting partial results information if the protocol and/or statistical analysis plan was amended since the previous submission of partial results information for that clinical trial. Final § 11.44(d)(3)(ii) specifies that the responsible party is required to submit information to reflect any changes in the status of certain agreements between the principal investigator and the sponsor if that information has changed since the previous submission of partial clinical trial results information.

§ 11.44(e)—Extensions for Good Cause

Overview of Proposal

Proposed § 11.44(e) outlined procedures for requesting extensions of the deadline for submitting results information for good cause. Section 402(j)(3)(E)(vi) of the PHS Act authorizes the Director to "provide an extension of the deadline for submission of clinical trial [results] information . . . if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted." We interpreted this authority as allowing the Director to grant an extension of any results information submission deadline that may be in effect for a given applicable clinical trial specified in proposed subpart C (*e.g.,* the general 12 month results information submission deadline); a delayed submission deadline established by the submission of an appropriate certification under section 402(j)(3)(E)(iii) of the PHS Act; or an extended deadline established by a previously granted extension. As for the latter, section 402(j)(3)(E)(vi) of the PHS Act explicitly allows the Director to "grant more than one extension for a clinical trial." (79 FR 69636)

Section 402(j)(3)(E)(vi) of the PHS Act does not define "good cause." Similarly, the proposed rule did not contain specific proposals for determining which situations would and would not be considered good cause for an extension. Instead, we indicated our intention to develop guidance (which would be subject to public comment) as the Agency gained more experience with extension requests and to communicate with the regulated community via other channels, including the *ClinicalTrials.gov* Web site. We intend to issue guidance on what might be considered "good cause" under particular circumstances as soon as practicable. In order to assist responsible parties who are considering submitting an extension request, we stated our intention to prepare, update periodically, and post on *ClinicalTrials.gov* a non-exhaustive list of reasons that the Agency generally will consider to be "good cause" and not "good cause" for granting an extension under section 402(j)(3)(E)(vi) of the PHS Act and proposed § 11.44(e). Such a list would contain those reasons that we consider would serve as useful examples for responsible parties of other applicable clinical trials. We also indicated that all extension requests would be considered on a case-by-case basis, and any generalizable conclusions that can be drawn from the granting or denial of a request may be added to the list of good causes and not-good causes for granting extensions (79 FR 69636).

In general, we indicated that there are likely to be only a few situations that would constitute good cause under section 402(j)(3)(E)(vi) of the PHS Act and proposed § 11.44(e) and listed the two situations that we have identified to date that we proposed would constitute good cause:

(1) The need to preserve the scientific integrity of an applicable clinical trial for which data collection is ongoing, including situations in which the submission of results information for the primary outcome(s) of an applicable clinical trial would impair or otherwise bias the ongoing collection, analysis, and/or interpretation of data for secondary outcome(s). We indicated our belief that an extension should be granted only in those situations in which the following could be demonstrated: Data collection for the secondary outcome(s) of interest extends more than 1 year beyond the completion date, the secondary outcome(s) is pre-specified in the protocol or SAP, and the planned analysis of the outcome measure is also described in the protocol or SAP. We noted that the responsible party could provide this information either by voluntarily submitting copies of the protocol or statistical analysis plan with the extension request or describing them in the extension request itself.

(2) Emergencies that would prevent timely submission of clinical trial results information, including situations in which one or more data collection sites were affected by natural disasters or other catastrophes outside the responsible party's or sponsor's control. In such cases, we indicated that we would generally expect to grant the responsible party an initial extension of up to 6 months, after which time additional extensions could be granted, as necessary. We generally would not consider events that might reasonably have been avoided or anticipated through standard contingency planning (*e.g.,* transition planning for key staff members who leave an organization) to constitute good cause for an extension under section 402(j)(3)(E)(vi) of the PHS Act or proposed § 11.44(e) (79 FR 69637).

To clarify what we believed would not ordinarily constitute good cause, we discussed two scenarios in the proposed rule's preamble. First we pointed out that a request containing only a general statement without any specific reason for a delay in data analysis (*e.g.,* "data could not be analyzed fully within 12 months") would not be a good cause. Second, we indicated that "awaiting journal publication" would not constitute a good cause. We noted that the ICMJE has stated that results information submission to *ClinicalTrials.gov* in compliance with section 402(j) of the PHS Act will not be considered "prior publication" and will not preclude future publication [Ref. 2, 98]. We invited public comment on these specific situations and on more general criteria that could be used to determine what constitutes good cause for an extension (79 FR 69637).

Proposed § 11.44(e)(1) specified that a responsible party may submit a request for an extension to *ClinicalTrials.gov* at any time before any results information submission deadline established in proposed § 11.44(a), (b), or (c), if the relevant certification has been submitted; or § 11.44(f), for a pediatric postmarket surveillance of a device that is not a clinical trial. Consistent with section 402(j)(3)(E)(vi) of the PHS Act, our proposal would require an extension request to include a complete description of the reason(s) why results information cannot be provided according to the applicable deadline and an estimated date on which results information will be submitted. The submitted extension request would be reviewed by an Agency official designated by the Director (79 FR 69637).

Proposed § 11.44(e)(2) indicated that the Agency would notify the responsible party electronically whether the request has been granted and, if granted, the Agency-specified extended deadline by which results information must be submitted. If the extension request is denied, the responsible party may either submit an appeal to the Director or would submit results information by the later of the original deadline or 15 calendar days after the date the Agency sends the electronic notice of the denial to the responsible party (79 FR 69637).

Proposed § 11.44(e)(3) specified that a responsible party may appeal a denied extension request or the Agency-specified extended deadline by which results information must be submitted not later than 15 calendar days after the date the Agency sends the electronic notice of the denial. Responsible parties are required to submit a description of the reasons for the appeal with sufficient detail to allow for evaluation. If the appeal is granted, the responsible party must submit results information by the revised deadline set by the Director in the electronic notification. If the appeal is denied, the responsible party must submit results information by the later of the following: The original deadline, the Agency-specified extended deadline provided in the electronic notification, or 15 calendar days after the date the Agency sends the electronic notice of denial of the appeal to the responsible party (79 FR 69637).

We also noted that extensions would apply only in the context of applicable clinical trials subject to the results information submission requirements of section 402(j)(3) of the PHS Act because the extension provision specifically refers to results information submission under 402(j)(3)(E)(i) of the PHS Act. Accordingly, extensions do not apply to clinical trial results information that is submitted under section 402(j)(4)(A) of the PHS Act (*i.e.,* voluntarily submitted trials (see final rule § 11.60(a)(1)) and triggered trials (see final rule § 11.60(a)(2)(ii))) (79 FR 69636).

Posting of Information About Certifications for Delayed Submission and About Extensions for Good Cause

In the proposed rule, we suggested that there would be value in posting information on the *ClinicalTrials.gov* Web site about the specific mechanism that had been used to delay the submission of clinical trial results information for a particular applicable clinical trial (*i.e.,* an extension request had been granted under proposed § 11.44(e) or the responsible party had submitted a certification for delayed submission, specifying either proposed § 11.44(b) or (c)). Doing so would provide a way to track the progress of clinical trials by informing users why clinical trial results information is not yet publicly available. Without such an indication, users who view a posted clinical trial record that contains no results information more than 1 year after the primary completion date might be led to believe, incorrectly, that the responsible party has not complied with the results information submission requirements of this proposed rule or that the Agency has failed to post such information. However, we recognized that information about the specific mechanism used to delay results information submission might in some circumstances be considered confidential (*e.g.,* the fact that the manufacturer had submitted or was planning to submit within 1 year a marketing application or premarket notification to FDA for a new use of a drug or device that was studied in the applicable clinical trial prior to any public statement by the or manufacturer about its plans).

In order to balance the competing interests, we proposed posting only minimal information about delayed results information submissions in these circumstances. That is, whether a responsible party delayed results information submission via certification or is granted an extension of the deadline, we would indicate in the posted record only that results information submission has been delayed, but not which mechanism had been used. As described previously, we proposed posting and updating periodically on the *ClinicalTrials.gov* Web site a generalized list of reasons for which extensions have and have not been granted (without information that might allow a user to identify a specific applicable clinical trial) to provide responsible parties with insight into the types of reasons that have and have not been considered to constitute good cause for an extension (79 FR 69638).

We invited public comments on our overall proposed approach and on the advantages and disadvantages of providing more specific information about extension requests (*e.g.,* whether submission was delayed via extension or certification), including alternative approaches that we could take that would provide more information to the public about the reasons for delayed submissions of clinical trial results information. We also invited public comment on whether extension requests could be submitted without containing any information that would be considered confidential (79 FR 69638).

Comments and Response

Commenters addressed the proposed approach for implementing extensions of the results information submission deadline in § 11.44(e). One commenter suggested that 15 calendar days do not provide sufficient time for a responsible party either to submit a written letter to appeal a denial for an extension request or to submit results information following notification that an appeal has been denied as proposed in § 11.44(e)(3)(i) and (vi), respectively. We note that several other commenters requested more broadly that the 15 calendar day deadlines proposed in the proposed rule be changed to 30 calendar day deadlines in the final rule (see discussion of § 11.64 in Section IV.D.3 of this preamble). The Agency generally agrees with the commenters and has changed, where possible, the 15 calendar day deadlines in the proposed rule to 30 calendar day deadlines in the final rule (see Section IV.D.3 of this preamble).

One commenter requested clarification that extension requests are not subject to any limitations in time, in contrast to the 2-year limitation for delayed submission of results with certification as specified in proposed § 11.44(b)(2) and (c)(2). We clarify that requests for extensions of the results information submission deadline are not subject to a time limit and may include estimated submission dates over 2 years after the date of the request. However, all submitted requests must provide a sufficient description of the reason(s) for proposing the particular estimated submission date. We also note that, because the statute and final rule permit the Director to grant more than one extension, a final extended results information submission deadline may exceed more than 2 years, even if the initial extension did not.

Several commenters suggested additional good cause reasons, such as for trials of device products that have received either a non-substantially equivalent or non-approval letter from the FDA, for preparation and analysis of data from large and complex trials, and for pending publication of trial results. One commenter requested clarification regarding the circumstances under which a sponsor of an applicable clinical trial of an unapproved, unlicensed, or uncleared product could request an extension. Another commenter proposed limiting the situations that would be considered "good cause" to national emergencies or catastrophic events. As stated in the proposed rule and this preamble, the Agency plans to prepare and periodically update a public, non-exhaustive list of reasons that it considers to be "good cause" and "not good cause." At present, we have identified only two general situations that we believe would constitute good cause: (1) The need to preserve the scientific integrity of a trial; and, (2) emergencies outside the control of a responsible party that would prevent timely submission, such as natural disasters or other catastrophes. In addition, we reiterate that we generally believe that pending publication and delays in data analysis for unspecified causes would not be considered good cause. We also note that requests for good cause may be submitted to extend any type of results information submission deadline, including the standard submission deadlines in § 11.44(a) (*i.e.,* 1 year after the primary completion date).

One commenter proposed that responsible parties submitting requests for extensions not be required to include confidential commercial or proprietary information. This commenter also requested that *ClinicalTrials.gov* provide a way for the public to distinguish between applicable clinical trials with missing results submissions because of missed regulatory deadlines (*i.e.,* late submissions) and those for which an extension has been granted, as required in § 11.44(e). Although we do not believe that confidential commercial or proprietary information will generally need to be submitted, the responsible party must provide in a submitted request for an extension "sufficient detail to allow for the evaluation of the request" as stated in final § 11.44(e)(1)(ii)(A). The Agency will not post detailed information about the request publicly and retains its plan to post minimal information on posted records to notify users when results information submission has been delayed without specifying whether a certification or extension mechanism was used. The Agency believes this approach will provide sufficient and appropriate information to the public to explain the reason for delay (see discussion above on § 11.44(b), (c), and (e)).

One commenter suggested that the final rule provide members of the public, including third-party researchers, the ability to appeal any reasons given for delaying the submission of results and that any such appeals be made publicly available with contact information. The Agency does not agree with this approach. We do plan, as proposed, to post publicly a list of general reasons provided in requests for extensions which the Agency considers to be "good cause" and "not good cause."

Regarding the proposal to post on *ClinicalTrials.gov* a list of general reasons the Agency will consider to be "good cause" and "not good cause" for granting extensions, one commenter requested that the actual reasons cited in extension requests submitted by responsible parties not be posted while two other commenters suggested that all submitted justifications and estimated submission dates be posted publicly for greater transparency. Another commenter proposed requiring the posting of submitted information for extension requests no later than 30 calendar days after receipt. As stated in the proposed rule and in this preamble above, the generalized list of reasons for which extensions have and have not been granted that is to be posted and updated periodically on *ClinicalTrials.gov* will *not* include any information that might allow a user to identify a specific applicable clinical trial. The intent is to provide responsible parties and members of the public with insight into the types of reasons that have and have not been considered to constitute good cause for an extension. We believe that this approach provides sufficient information about the process for requesting extensions for good cause.

Final Rule

Final § 11.44(e) largely retains the proposal outlined in the NPRM with the following exceptions. First, the final rule replaces the 15 calendar day deadlines (*e.g.,* for submission of results information or an appeal after a request is denied) as proposed in the proposed rule with 30 calendar days in the final rule in response to public comments. Second, the final rule clarifies that some applicable clinical trials may be subject to section 402(j)(3)(E)(vi) of the Public Health Service Act. Third, the final rule adds § 11.44(e) to the list of provisions in § 11.44(e)(1)(i) and § 11.44(e)(2)(ii) regarding the submission deadlines that would otherwise apply. Fourth, formatting changes are made for consistency and clarity. Final § 11.44(e)(1) stipulates that extension requests must be submitted to the Agency via direct electronic submission to *ClinicalTrials.gov* prior to the date on which results information would otherwise be due in accordance with the results information submission deadlines, including one for a previously-granted extension request. Responsible parties are required to submit a description of the reasons that they believe constitute good cause to justify an extension and an estimated extended results information submission date with sufficient detail to allow for evaluation of both requested components.

Under § 11.44(e)(2), a response to the extension request will be communicated electronically via *ClinicalTrials.gov* to the responsible party, providing notice as to whether or not the requested extension has been granted. If a request is granted because it demonstrates good cause, a revised deadline for results information submission will be communicated in the notice. If a request is denied, the deadline for submitting results is the later of the deadline (*e.g.,* 1 year after the primary completion date or the delayed submission deadline if a certification has been filed under subparts (b) or (c)) or 30 calendar days after the date the electronic notice of the denial of the request is sent to the responsible party.

Section 11.44(e)(3) specifies that a responsible party who appeals a denied extension request must submit the appeal to the Director in the format specified at *https://prsinfo.clinicaltrials.gov/* (or successor site) not later than 30 calendar days after the date on which electronic notification of the granting or denial of the request was sent to the responsible party. The appeal must explain why, in the view of the responsible party, the initial decision to deny an extension request or to grant an extension request with a shorter deadline than requested by the responsible party should be overturned or revised (*e.g.,* by providing further elaboration of the grounds for the request or by highlighting factors that justify an extension). Generally, new information should not be submitted upon appeal. The submitted appeal will be considered by the Director or his delegate. If an appeal is granted, a revised deadline for results information submission will be set by the Director and provided to the responsible party in an electronic notification. If the appeal is denied, the deadline for submitting results information will be the later of the original submission deadline or 30 calendar days after the electronic notification of the denial of the appeal is sent to the responsible party. If the appeal of an extension request that was granted with a shorter deadline than was originally requested is denied, the deadline for submitting results information is the later of the deadline specified in the notification granting the extension request or 30 calendar days after the electronic notification of the denial of the appeal is sent to the responsible party.

We note that if the estimated primary completion date is earlier than the actual (or current estimated) primary completion date, a responsible party must update the estimated primary completion date in the clinical trial record to reflect the actual (or revised estimated) primary completion date within 30 calendar days, as required by § 11.64(a)(1)(ii)(I), but should *not* request an extension based on the outdated primary completion date. The fact that the responsible party has updated the primary completion date will be reflected in *ClinicalTrials.gov,* consistent with the handling of all updates under § 11.64.

Posted records of trials that have been granted certification for delayed submission or extension will indicate that results information submission has been delayed by displaying minimal information. This will provide significant information for users to know whether a trial has met the requirements for results information submission under the final rule. As soon as practicable, we will post on the *ClinicalTrials.gov* Web site, and periodically update, a list of reasons for which extensions have and have not been granted to provide responsible parties and the public with insight into the types of reasons that have and have not been considered to constitute good cause for an extension. We note that entries on this list will not contain any information that might allow a user to identify a specific applicable clinical trial.

§ 11.44(f)—Pediatric Postmarket Surveillance of a Device That Is Not a Clinical Trial

Overview of Proposal

We proposed in § 11.44(f) that results information for a pediatric postmarket surveillance of a device that is not a clinical trial be submitted not later than 30 calendar days after the date that the final report is submitted to FDA. We believe that 30 calendar days provide sufficient time to allow the responsible party to format and submit the information as required by this part.

We noted in the NPRM that we recognize that the proposed deadlines for submitting clinical trial results information under proposed § 11.44(a)–(d) are not well adapted to a pediatric postmarket surveillance of a device that is not a clinical trial. Such surveillances generally do not have a completion date that can be easily measured by the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome. However, these surveillances will have a date on which a final report must be sent to the FDA, as specified in the approved postmarket surveillance plan (79 FR 69638).

Comments and Response

One commenter addressed proposed § 11.44(f) and suggested that the timeline submission requirement should apply as to § 11.44(a)–(d). We note that any pediatric postmarket surveillance of a device that is also a clinical trial would be subject to the results information submission deadlines that apply to clinical trials (*e.g.,* standard submission deadline in proposed § 11.44(a)). For a pediatric postmarket surveillance of a device that is not a clinical trial the proposed deadlines § 11.44(a)–(d) are not well adapted. Therefore, the final rule retains the deadline specified in proposed § 11.44(f).

Final Rule

Aside from clarifying that "device" means "device product" and that some surveillances that are not clinical trials may be subject to section 402(j)(C)(3) of the PHS Act, no changes were made in § 11.44(f) of the final rule, which requires the submission of results information not later than 30 calendar days after the date on which the final report of the approved pediatric postmarket surveillance of a device product as specified in 21 CFR 822.38 is submitted to FDA (*i.e.,* the primary completion date as defined in § 11.10(a)).

4. § 11.48—What constitutes clinical trial results information?

Overview of Proposal

Section 11.48(a) of the NPRM proposed the general requirements for clinical trial results information that would apply to an applicable clinical trial other than a pediatric postmarket surveillance of a device that is not a clinical trial. Proposed § 11.48(b) described the requirements for a pediatric postmarket surveillance of a device that is not a clinical trial. In specifying the results information that must be submitted for a clinical trial, proposed § 11.48(a) separated the data elements into the following general categories of information: (1) Participant flow, (2) demographic and baseline characteristics, (3) outcomes and statistical analyses, (4) adverse event information, (5) administrative information, and (6) additional results information for applicable device clinical trials of unapproved or uncleared devices. The proposal also indicated that whenever possible *ClinicalTrials.gov* will use information submitted during registration to pre-populate the column and row names of the tables of information that are required as part of results submission. We noted that doing so reduces the data entry burden on responsible parties and minimizes the possibility of clerical errors. However, in all cases, the responsible party is required to revise the information, as needed, so that the results information appropriately and accurately reflects the way that data were collected and analyzed in the clinical trial. Each of the categories of results information that are required to be submitted are addressed, in order, below (79 FR 69638).

Comments and Response

Numerous commenters addressed the requirements for clinical trial results information that would apply to an applicable clinical trial. The specific comments are described in the sections of § 11.48 to which they apply. We received one general comment in support of the proposed requirements for results information. We also received one general comment requesting that the Agency minimize the number of fields and amount of data required for clinical trial results information in order to provide responsible parties with more flexibility in reporting the results of different types of trials. Based on more than 7 years of experience operating the results database, we recognize the need for flexibility and generally agree with the commenter. The final rule represents our attempt to balance the statutory requirements with the minimum information needed to understand study results in a way that is consistent across clinical trials and with existing reporting standards, such as the CONSORT statement [Ref. 93] which are used to guide the publication of trial results in peer-reviewed literature.

§ 11.48(a)(1)—Participant Flow

Overview of Proposal

Proposed § 11.48(a)(1) addressed the statutory requirement for the submission of specified participant flow information as part of clinical trial results information. Section 402(j)(3)(C)(i) of the PHS Act specifies that a responsible party must submit "[a] table of . . . data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any." Consistent with this section of the PHS Act and pursuant to our authority under section 402(j)(3)(D)(iii)(IV) of the PHS Act, we proposed in § 11.48(a)(1) to require the submission of the following participant flow information: (1) Participant Flow Arm Information, (2) Pre-assignment Information, and (3) Participant Data. This information permits the construction of a table that shows the number of participants starting the clinical trial and the flow through completion of the trial. In our proposed approach, information about the number of participants excluded from the analysis would not be contained in the participant flow but would be submitted as part of the information about outcome measures specified and described in proposed § 11.48(a)(3). We also described how we intend to continue to provide responsible parties with a means of providing, on an optional basis, additional details about the participant flow in a manner consistent with CONSORT guidelines [Ref. 93] (79 FR 69639). We invited public comments on the value of providing additional information describing study periods (*e.g.,* wash-out, consecutive cycles of the intervention), particular milestones, and reasons for non-completion on *ClinicalTrials.gov* as well as comments on approaches for collecting this information.

Comments and Response

Commenters addressed specific aspects of the proposed requirements for participant flow information in § 11.48(a)(1). One commenter suggested requiring the submission of information on the number of participants that are enrolled and who complete the trial at the time that the trial ends (instead of at the time of clinical trial results submission). We agree with the commenter that the actual number of participants enrolled in the trial must be provided in a timely manner as specified in §§ 11.28 and 11.64. However, the number of participants completing the trial is considered clinical trial results information that must be submitted in accordance with section 402(j)(3)(C)(i) of the PHS Act and § 11.24. Another commenter suggested requiring the submission of information on the number of participants not completing the trial by sex and gender and in a standardized format, citing associated scientific principles. While we agree with the commenter on the potential value of such information, requirements regarding which data must be collected during a clinical trial are outside the scope of this rule. We therefore are not proposing to make submitting the requested participant flow information a requirement, but we do intend to evaluate ways to accommodate the submission of any such available information. We did not receive any comments on the value of providing additional information for describing study periods, milestones, and reasons for non-completion on *ClinicalTrials.gov* or on approaches for collecting this information. However, one commenter provided general support for providing Pre-assignment Information.

Final Rule

Taking into consideration the comments, as well as the statutory requirements for clinical trial results information, we are generally maintaining the approach for participant flow information described in the NPRM. However, we are providing clarification on certain aspects of the requirements, based on our operational experience and routine queries received from users. First, we provide additional elaboration to clarify the information that is required to be provided as part of the brief description of each arm. Second, we clarify the definition of Pre-assignment Information in § 11.48(a)(1)(ii). The proposed definition indicated that Pre-assignment Information consists of "[a] description of significant events affecting the number of human subjects enrolled in the clinical trial but not assigned to an arm, if any." The phrase "affecting the number of" may incorrectly imply that the actual number of human subjects enrolled changes based on a pre-assignment event. Instead, the intent is to describe events that occur between enrollment and assignment to an arm that are planned as part of the study design and other events that lead to differences in the number of human subjects enrolled and the number of human subjects assigned to an arm. Third, we explain the terms "started" and "completed," which are used to describe Participant Data in § 11.48(a)(1)(iii). Fourth, we address requirements for clinical trials that assign participants to arms based on units other than participants (*e.g.,* lesions, eyes, implants). While the NPRM included a proposal for how such information is specified when reporting an outcome measure in § 11.48(a)(3)(ii), Analysis Population Information, it did not address similar information in § 11.48(a)(1), Participant flow and § 11.48(a)(2) Demographic and baseline characteristics.

Final § 11.48(a)(1) requires the submission of the following participant flow information: (1) Participant Flow Arm Information, consisting of "[a] brief description of each arm used for describing the flow of human subjects through the clinical trial, including a descriptive title used to identify each arm"; (2) Pre-assignment Information, consisting of "[a] description of significant events in the clinical trial that occur after enrollment and prior to assignment of human subjects to an arm, if any"; and (3) Participant Data, which is "[t]he number of human subjects that started and completed the clinical trial, by arm. If assignment is based on a unit other than participants, also include a description of the unit of assignment and the number of units that started and completed the clinical trial, by arm." This information permits the construction of a table that shows the flow of participants through the clinical trial, with each participant represented in only one arm. Information about the number of participants excluded from the analysis is not contained in the participant flow; it is submitted as part of the information about outcome measures (§ 11.48(a)(3), Outcomes and statistical analyses). *ClinicalTrials.gov* will use the Arm Information, Intervention Name, and Intervention Description data elements (submitted as part of clinical trial registration information) to provide the responsible party with an option for pre-populating table column names and descriptions for Participant Flow Arm Information. The responsible party will review and edit the information as needed to ensure that it appropriately and accurately reflects the participant flow for the clinical trial, or the responsible party may instead define new arms to reflect how participants were assigned to arms. In general, the Participant Flow Arm Information must include all arms to which participants were assignedand must contain sufficient details to understand the arms to which participants were assigned and the intervention strategy used in each arm. The amount and level of detail are similar to what is described in § 11.10(b) for the arm and intervention data elements that are used to pre-populate Participant Flow Arm Information.

Pre-assignment Information is collected in a free text field to allow the responsible party to explain significant events that occur between the enrollment of human subjects and their assignment to an arm. These events may be planned as part of the study design or unplanned. An example of a significant event that is planned as part of the study design is a run-in period during which all participants receive an intervention, which may result in identifying participants who are not eligible to continue in the study or may otherwise influence assignment to an arm. An example of an unplanned event is the voluntary withdrawal of a participant prior to assignment to an arm. Either event may result in the number of human subjects starting the trial (*e.g.,* assigned to an arm) being fewer than the total number of human subjects enrolled. Pre-assignment Information is where the responsible party describes any such differences. As part of Participant Data, the responsible party provides the number of human subjects that started and completed each arm. The number of participants that "started" the clinical trial means the number of participants assigned to the arm (regardless of whether these participants received the assigned intervention). The meaning of the number of participants that "completed" the arm may vary, based on the specific context of the clinical trial. However, if there is more than one period (*e.g.,* a discrete stage) in the clinical trial, the meaning of the number of participants starting and completing is in the context of initial assignment and the specific period. Specifically, "started" in the first period (and the overall clinical trial) means the number of participants assigned to each arm, and "started" in subsequent periods (if any) means the number of participants initiating each period of the clinical trial in each arm. In order to retain the flexibility desired by responsible parties in reporting results, we do not intend to define this further. However, we will implement an optional data element to allow responsible parties to explain the meaning of "started" and/or "completed" in the context of their specific clinical trial. If the assignment of participants to an arm is based on a unit other than human subjects (*e.g.,* lesions, eyes, implants), the responsible party must also provide, in addition to participants, the type and number of units that started and completed the clinical trial, by arm. Based on our experience with submitted results information and routine queries from users of *ClinicalTrials.gov*, this information is necessary for accurately representing the assignment strategy and for interpreting similar information on the units analyzed in Analysis Population Information for Demographic and baseline characteristics in § 11.48(a)(2)(ii) and Outcomes and statistical analyses in § 11.48(a)(3)(ii). Therefore, consistent with section 402(j)(3)(C)(i) of the PHS Act and pursuant to our authority under section 402(j)(3)(D)(iii)(IV) of the PHS Act, final § 11.48(a)(1) requires the submission of the following participant flow information: (1) Participant Flow Arm Information, (2) Pre-assignment Information, and (3) Participant Data.

Although we did not receive any comments in response to our request for comment on the topic of describing study periods, milestones, and reasons for non-completion on *ClinicalTrials.gov*, we intend to continue to provide responsible parties with a means of submitting, on an optional basis, additional details about the participant flow in a manner consistent with CONSORT guidelines [Ref. 93]. This information consists of details about the flow of participants through different periods or milestones defined for the clinical trial and the reason(s) why participants did not complete the clinical trial or reach a particular milestone. Clinical trials often proceed through multiple periods (*e.g.,* wash-out, consecutive cycles of the intervention), and having information about the participant flow in each period and the reasons why participants did not complete the clinical trial or reach a particular milestone, if applicable, improves users' understanding of the clinical trial results data. Clinical trials vary considerably in their design, and some may not include specific periods or milestones. However, when a study does include such aspects, we will continue to encourage responsible parties to provide clinical trial results information in a manner that most clearly describes the study design and what happened to participants as they progressed through the study. We intend to provide additional guidance, including case examples, to help responsible parties understand how to optimally present various study designs.

§ 11.48(a)(2)—Demographic and Baseline Characteristics

Overview of Proposal

Proposed § 11.48(a)(2) addressed the statutory requirement for the submission of demographic and baseline characteristics as part of clinical trial results information. Section 402(j)(3)(C)(i) of the PHS Act specifies that a responsible party must submit "[a] table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial . . ." (79 FR 69639). Consistent with this section of the PHS Act, the Agency proposed in § 11.48(a)(2) to require "[i]nformation for completing a table of demographic and baseline measures and data collected by arm or comparison group and for the entire population of human subjects who participated in the clinical trial." The information must include the following: (i) Baseline Characteristics Arm/Group Information; (ii) Overall Number of Baseline Participants; (iii) Baseline Measure Information, to include the Name and Description of the measure, Measure Type, Measure of Dispersion, and Unit of measure; and (iv) Baseline Measure Data. We further proposed that Baseline Measure Information must include "[a] description of each baseline or demographic characteristic measured in the clinical trial, including age, gender, and any other measure(s) that were assessed at baseline and used in the analysis of outcome measures in accordance with § 11.48(a)(3)." We invited public comment on the sufficiency of this proposed approach for submitting baseline characteristics as well as whether we should require the submission of additional demographic or baseline characteristics collected during the clinical trial that are common across many trials, such as country-of-origin or country-of-residence. We also invited comment on whether the list of proposed choices for measures of central tendency and of dispersion was adequate to provide an accurate description of the measures used in any clinical trial (79 FR 69640).

Comments and Response

Commenters addressed specific aspects of the proposed requirements for demographic and baseline characteristics in § 11.48(a)(2). One commenter provided general support for the proposed baseline characteristics requirements. Some commenters supported adding a requirement for reporting race and ethnicity information, with several commenters citing similar FDA and NIH requirements. One commenter stated that having race and ethnicity information was important for different groups "seeking to understand how representative minority populations are in [applicable clinical trials] . . ." Some of these commenters also recommended including an option to specify that race and ethnicity information was not collected. While we did not propose to require race and ethnicity information because of a concerns that this information may not be routinely collected during all clinical trials, we agree that providing the responsible party with a mechanism to indicate that race and/or ethnicity information was not collected would address this concern. Therefore, the final rule adds a requirement for the reporting of race and ethnicity information, or an indication that such information was not collected during the trial, as a component of Baseline Measure Information. The final rule follows the same approach to indicating that information was not collected during the trial as for other baseline measures required by *ClinicalTrials.gov* (*e.g.,* age, sex/gender). One commenter indicated that country of origin information "could be an important data point" to require but did not provide further elaboration on why it is important. Although it may be important for some clinical trials, in considering other commenters concerns about additional requirements (noted below) as well as the addition of a requirement to submit race and ethnicity informatoin, we are not persuaded that the benefits of requiring country-of-origin information would outweigh the burdens. However, we will, continue to make available "region of enrollment" as part of the limited list of options for Baseline

Measure Information to facilitate the optional reporting of such information if it was assessed at baseline. One commenter recommended that the term "gender" be replaced by "sex." We partially addressed this issue in § 11.10, and to address the same issue in the context of clinical trial results information, we are revising the term "gender" to "sex/gender" to indicate that the submission of Baseline Measure Information on sex and/or gender would meet the requirement. Other commenters opposed any additional requirements for demographic information, citing concerns that expanded reporting requirements would lead to future requirements to collect such data during a trial. As explained in proposed § 11.48(a)(2)(iii), only summary data for measures assessed at baseline are required to be reported, and the final rule does not impose requirements on the design or conduct of clinical trials or on the data that must be collected during clinical trials.

After consideration of the comments, we believe it is appropriate in the final rule to limit the requirement to report any measure(s) assessed at baseline and used in the analysis of outcome measure(s) in § 11.48(a)(2)(iii) to those baseline measure(s) used in the analysis of primary outcome measure(s). One commenter suggested that baseline measures related to outcome measures be reported as part of outcome measure information in proposed § 11.48(a)(3). We acknowledge that, in limited circumstances, the arms or groups used for demographics and baseline characteristics may differ from those used in the primary outcome measure and agree with the commenter that providing such Baseline Measure Information as part of Outcome Measure Information would be appropriate in such circumstances. When relevant, the final rule also permits the reporting of baseline measure information as a component of both demographic and baseline characteristics in § 11.48(a)(2) as well as outcomes and statistical analyses in § 11.48(a)(3). In addition, we will continue to evaluate methods for displaying results information on ClinicalTrials.gov to improve linking these two relevant sections when the baseline and outcome measures are related.

Based on our experience with submitted results information and routine queries from users, we note that some clinical trials include baseline measures and outcome measures that are based on units of analysis other than participants. While the NPRM did not address how such information could be specified in proposed § 11.48(a)(2), Demographic and baseline characteristics, it did include a proposal for reporting such information as an outcome measure in § 11.48(a)(3)(ii) Analysis Population Information. To address this inadvertent omission and facilitate the accurate submission of Baseline Measure Information and Baseline Measure Data in a manner that is consistent with the design, conduct and analysis of the clinical trial, the final rule adds similar data elements to § 11.48(a)(2) for the limited cases in which units of analysis are other than participants (*e.g.,* lesions, eyes, implants). We also note that if such a requirement were not added, it would not be possible for a responsible party to submit baseline measure(s) that were assessed at baseline and used in the analysis of the primary outcome measures(s), when the unit of analysis for the primary outcome measure(s) is other than participants. We also add an element to describe the analysis population when the Overall Number of Baseline Participants (or units) differs from the number of human subjects (or units) assigned to an arm or comparison group, similar to Analysis Population Description in § 11.48(a)(3)(ii)(C). Analysis Population Description was added to Demographic and baseline characteristics as an optional data element in January 2013 in response to queries routinely received from responsible parties as well as our experience with submitted results information. Based on a review of clinical trials with results posted on *ClinicalTrials.gov,* the number of participants analyzed in Demographic and baseline characteristics differed from the number assigned to an arm in 15 percent of clinical trials. The addition of this data element is therefore necessary to enable users of *ClinicalTrials.gov* to understand why some participants (or units) were excluded from the analysis of Demographic and baseline characteristics. These data elements in final § 11.48(a)(2) are consistent with section 402(j)(3)(C)(i) of the PHS Act and are promulgated pursuant to our authority under section 402(j)(3)(D)(iii)(IV) of the PHS Act.

We invited comments on whether the lists of proposed choices for Measure Type and Measure of Dispersion were adequate, but we did not receive any specific comments on this topic. However, based on our experience with submitted results information and routine queries from users of *ClinicalTrial.gov,* we have identified two issues with the following limited list of options for Measure Type proposed in the NPRM preamble: "Number," "mean," "median," "least squares mean," "geometric mean," and "log mean." First, because the "log mean" option is not needed, we have excluded it from the limited list of options for Measure Type. Of the more than 22,000 records with posted results on *ClinicalTrials.gov* as of July 2016, only 3 indicated "log mean" in Baseline Measure Information, and in each case the data were the mean of log transformed data (rather than a logarithmic mean) and should have been specified as a Measure Type of "mean" instead. Second, as discussed in this preamble for Outcome measures and statistical analyses, we also add "geometric least squares mean" to the list of options for Measure Type. Third, the "number" option is not sufficiently granular to allow for discrimination among different methods of aggregation that use "number" for Measure Type (such as count of participants or percentage of participants). To address this, we are adding two additional options to Measure Type to specify whether the number is a "count of participants" or a "count of units." These choices will improve the clarity of results data by making such counts unambiguous, thereby ensuring that these data are properly interpreted by human users as well as (semi-) automated systems.

Final Rule

Taking into consideration the comments, our experience with the *ClinicalTrials.gov* data bank, and the statutory requirements for clinical trial results information, we are modifying the NPRM approach for Baseline Measure Information to specify that Demographic and baseline characteristics includes a new requirement to provide race and ethnicity information, if collected, or indicate that it was not collected, and modifies the requirement to provide other measures assessed at baseline to those used in the analysis of a primary outcome measure. In addition, based on our operational experience and routine queries from users, we add provisions in final § 11.48(a)(2)(ii), Baseline Analysis Population Information to address how the responsible party provides demographic and baseline characteristics when the unit of analysis is not human subjects and how to describe the analysis population, if needed. Final § 11.48(a)(2)(v) also explains how to specify the number of baseline participants (and units) analyzed, if different from the Overall Number of Baseline Participants or Units Analyzed. Additional elaboration is provided on the information required to be submitted as a brief description of each arm/group (a similar omission was described for § 11.48(a)(1)), the use of "categories" used to submit Baseline Measure Data, and options for specifying Measure Type. We have made minor revisions to clarify the Name and description of the measure in final § 11.48(a)(2)(iii)(A) to indicate that the information must include "any categories that are used to submit Baseline Measure Data" (revised from the proposed broader phrasing of "any categories that are used in submitting results"). We also have revised the description of the population for whom Baseline Measure Data is provided in § 11.48(a)(2)(iv) (proposed "human subjects who participated in the clinical trial") to be consistent with a similar description for Overall Number of Baseline Participants in § 11.48(a)(2)(ii)(A) ("human subjects for whom baseline characteristics were measured"). Final § 11.48(a)(2) requires the submission of the following demographic and baseline characteristic information: (i) Baseline Characteristics Arm/Group Information; (ii) Baseline Analysis Population Information; (iii) Baseline Measure Information; (iv) Baseline Measure Data; and (v) Number of baseline participants (and units), if different from Overall Number of Baseline Participants or Units Analyzed.

ClinicalTrials.gov will use the Arm Information, Intervention Name, and Intervention Description data elements (submitted as clinical trial registration information) as well as Participant Flow Arm Information to provide the responsible party with options for pre-populating table column names and descriptions for Baseline Characteristics Arm/Group Information (described in final § 11.48(a)(2)(i)). The responsible party will review and edit the information as needed to ensure that it appropriately and accurately reflects the baseline arms/groups for the clinical trial, or the responsible party may instead define new groups to reflect how baseline information was analyzed. As described in the discussion of the term "comparison group" in § 11.10(a) of the preamble, the reference to comparison groups recognizes that when data collected during clinical trials are analyzed, the data are often aggregated into groupings of human subjects (*i.e.*, comparison groups) other than the arms to which the subjects were assigned for the study. It is expected that Baseline Characteristics Arm/Group Information will be the same as Participant Flow Arm Information, unless human subjects were analyzed in groups that are different from those to which they were assigned. In this situation, there must be sufficient detail to understand how the arm(s) or comparison groups used for submitting Baseline Characteristics Arm/Group Information were derived from Participant Flow Arm Information. In general, Baseline Characteristics Arm/Group Information must include all participants assessed at baseline, with each participant belonging to only one arm or comparison group, as specified in the pre-specified protocol and/or SAP. Baseline Characteristics Arm/Group Information must also include sufficient detail to understand the intervention strategy being described in that arm/group, similar to what is described in this preamble for Participant Flow Arm Information in § 11.48(a)(1).

Baseline Analysis Population Information, as described in final § 11.48(a)(2)(ii), consists of (A) Overall Number of Baseline Participants, (B) Overall Number of Units Analyzed, and (C) Analysis Population Description. Baseline Analysis Population Information is similar to that described for Analysis Population Information for outcome measures in § 11.48(a)(3)(ii). The Overall Number of Baseline Participants is defined as the "[t]he total number of human subjects for whom baseline characteristics were measured, by arm or comparison group, and overall." Overall Number of Baseline Participants is necessary to indicate whether some subjects enrolled in the clinical trial were not measured at baseline (*e.g.*, because they dropped out of the clinical trial before that point in time) and to help ensure that results information is submitted for all subjects who were measured at baseline. If any of the demographic or baseline characteristics are based on a unit other than human subjects (*e.g.*, lesions, eyes, implants), the responsible party is also required to provide the Overall Number of Units Analyzed, which is defined as ". . . a description of the unit of analysis and the number of units for which baseline measures were measured and analyzed, by arm or comparison group and overall." In addition, the Analysis Population Description in baseline must be used "[i]f the Overall Number of Baseline Participants (or units) differs from the number of human subjects (or units) assigned to the arm or comparison group and overall, [with] a brief description of the reason(s) for the difference."

Baseline Measure Information, as described in § 11.48(a)(2)(iii), consists of "[a] description of each baseline or demographic characteristic measured in the clinical trial, including age, sex/gender, race, ethnicity (if collected under the protocol), and any other measure(s) that were assessed at baseline and are used in the analysis of the primary outcome measure(s) in accordance with § 11.48(a)(3)." If any Baseline Measure Information (described in § 11.48(a)(2)(iii)) is not measured in the clinical trial (*e.g.*, age, sex/gender, race and ethnicity), *ClinicalTrials.gov* will provide a mechanism for the responsible party to indicate that such information was not collected. A responsible party must submit demographic and baseline characteristics using the following limited list of options for Baseline Measure Information: "Age," "sex/gender," "race and ethnicity," "region of enrollment" (if assessed at baseline), and "study-specific measure(s)," by arm or comparison group and overall for the clinical trial. Age information must be submitted as "age, continuous" (*e.g.*, for Measure Types of "mean" or "median"), "age, categorical" (pre-defined categories of <18 years, 18 to 65 years, and >65 years), or "age, customized" (age categories defined by responsible party). For sex/gender data, the responsible party must submit using "sex, male, female" (pre-formatted categories of male and female) and/or "gender, customized" (gender categories defined by the responsible party). The responsible party may use the description of the measure to provide additional, free-text information about the collection and/or reporting methods used for sex and/or gender information. Race and ethnicity data must be submitted as "race (NIH/OMB)," "ethnicity (NIH/OMB)," or "race/ethnicity, customized." The options that reference NIH/OMB reflect the classification system of the Office of Management and Budget (OMB) (see 62 FR 58782, Oct. 30, 1997), which has been adopted by Federal agencies, including NIH. Alternatively, the responsible party may select "race/ethnicity, customized" in order to customize race and ethnicity categories for consistency with how information was collected in the protocol for the clinical trial, if different from the NIH/OMB classification. If region of enrollment information is provided, the measure information will be pre-filled with the countries described for Facility Information in § 11.28(a)(2)(iii)(C), but this information can be edited as needed. Responsible parties must select from this limited list of options for Baseline Measure Information to ensure that the required information is provided and to allow for the identification of such information in a search by users of the public site. In addition, *ClinicalTrials.gov* accommodates the submission of information to describe an unlimited number of customized demographic and baseline characteristics (using the "study-specific measure" option). In general, we cannot specify in advance which other demographic and baseline characteristics would be provided for a particular clinical trial. Only those conducting the clinical trial will know which characteristics are important for their clinical trial and which were actually collected. Important demographic and baseline characteristics are those that a responsible party determines are useful for comparing participants across comparison groups and for describing the population enrolled in the clinical trial. Although we cannot specify these characteristics in advance, we do believe it is important that baseline measures include any characteristic used in assessing primary outcome measure(s). For example, if an outcome measure compares a subject's blood pressure after 6 weeks of receiving a particular intervention, the baseline measure of blood pressure must be submitted. Similarly, if a clinical trial includes a statistical analysis of a primary outcome measure that uses baseline data from participants enrolled in the clinical trial as part of the calculation (*e.g.,* a regression analysis), it is necessary to submit the relevant baseline data. The use of these baseline data in analyzing the primary outcome measure indicates that these data would have been collected during the clinical trial and would be important to the interpretation of results. In the limited circumstance in which Baseline Characteristics Arm/Group Information is different from the Arms/Groups used in the analysis of the primary outcome measure(s), it is acceptable to provide the relevant Baseline Measure Information only as part of Outcome Measure Information.

For each measure, Baseline Measure Information in § 11.48(a)(2)(iii) must include the following elements: "(A) Name and description of the measure, including any categories that are used to submit Baseline Measure Data; (B) Measure Type and Measure of Dispersion [for] each baseline measure submitted, an indication of the type of data to be submitted and the associated measure of dispersion; [and] (C) Unit of Measure." Providing Baseline Measure Information in this structured manner is intended to ensure that the information is meaningful to users, ensure that submitted information is complete, and improve the comparability of information across clinical trials. With respect to the categories that are used to submit Baseline Measure Data, in our experience operating *ClinicalTrials.gov,* we have observed that responsible parties use categories for two general types of information: Either a list of mutually exclusive and exhaustive categories to which each participant belongs to one and only one (*e.g.,* participants with history of smoking, no history of smoking, unknown) or a list of items that are not mutually exclusive and exhaustive for which a single participant may be represented in more than one row (or not all) (exposure to "A," "B," and/or "C"). To distinguish these two different types of information and to allow for improved options for validation (*e.g.,* the system can ensure that the sum of participants in mutually exclusive and exhaustive categories is the same as the overall number of baseline participants), responsible parties may indicate which information type is being reported. When specifying the Measure Type, the responsible party is required to select one option from the following limited list of options: "Count of participants," "count of units," "number," "mean," "median," "least squares mean," "geometric mean," and "geometric least squares mean." When specifying the associated Measure of Dispersion, the responsible party is required to select one option from the following limited list of options: "Standard deviation," "inter-quartile range," "full range," and "not applicable" (which would be permitted only if the specified measure type is "count of participants," "count of units," or "number"). No "other" option is available for either Measure Type or Measure of Dispersion, but responsible parties have the option of voluntarily providing additional information about the baseline measures as part of a free-text description of the baseline measure. Unit of Measure describes what is being quantified by the data (*e.g.,* blood pressure in "millimeters of mercury" or "participants"). Each baseline measure can have only one Unit of Measure.

Final § 11.48(a)(2)(iv) specifies that Baseline Measure Data consists of "[t]he value(s) for each submitted baseline measure, by arm or comparison group and for the entire population of human subjects . . ." Section 11.48(a)(2)(v) indicates that, for each submitted baseline measure, the number of baseline participants (and units) must be specified if different from the Overall Number of Baseline Participants or Overall Number of Units Analyzed (*e.g.,* a participant was unable to complete one of the baseline assessments). The "[n]umber of baseline participants (and units)" is provided "by arm or comparison group and overall" as part of Baseline Measure Data.

§ 11.48(a)(3)—Outcomes and Statistical Analyses

Overview of Proposal

Proposed § 11.48(a)(3) addressed the statutory requirement for the submission of outcomes and statistical analyses as part of clinical trial results information. Section 402(j)(3)(C)(ii) of the PHS Act specifies that a responsible party must submit "[t]he primary and secondary outcome measures as submitted under paragraph (2)(A)(ii)(I)(ll), and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures" (79 FR 69640). Consistent with this section of the PHS Act, the Agency proposed in § 11.48(a)(3) to require "[i]nformation for completing a table of data for each primary and secondary outcome measure by arm or comparison group, including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any." The NPRM noted that the information must include the following: (i) Outcome Measure Arm/Group Information; (ii) Analysis Population Information; (iii) Outcome Measure Information, to include the Name of the specific measure, Description of the metric, Time point(s) at which the measurement was assessed, Outcome Measure Type, Outcome Measure Reporting Status, Measure Type, to include type of data and related measure of dispersion or precision, and Unit of measure; (iv) Outcome Measure Data; and (v) Statistical Analyses information for results of scientifically appropriate statistical analyses. The NPRM included options that could be selected to describe the type of data and related measure of dispersion or precision and invited public comment on whether the proposed options were sufficient for collecting data from the full range of clinical trials that would be subject to the proposed rule. Statistical Analyses were proposed to be defined as "[r]esult(s) of scientifically appropriate statistical analyses, if any . . ." The criteria for what would be considered scientifically appropriate were proposed in § 11.48(a)(3)(v) as "including any statistical analysis that is: (A) Pre-specified in the protocol and/or statistical analysis plan [SAP] that was performed on the outcome measure data, (B) Made public by the sponsor or responsible party prior to the date on which results information is submitted for all primary and secondary outcome measures studied in the clinical trial, or (C) Conducted in response to a request made by the U.S. Food and Drug Administration prior to the date on which complete clinical trial results information is submitted for all of the primary outcome measures studied in the clinical trial." We invited public comment on these and other criteria that the Agency should consider when determining what constitutes a scientifically appropriate statistical analysis. Finally, the NPRM described approaches for reporting information for outcome measures and statistical analyses in the following situations: (1) When a trial is terminated before data are collected for one or more of the pre-specified outcome measures and (2) when outcome measure data are collected, but the actual enrollment falls well below the target enrollment. We invited public comments on other way to highlight the limitations of the submitted data when either situation occurs (79 FR 69643).

Comments and Response

Commenters addressed specific aspects of the proposed requirements for Outcomes and statistical analyses in § 11.48(a)(3). Most of the commenters addressed the proposed criteria for determining when a statistical analysis would be considered scientifically appropriate. Many of these commenters expressed concern that the proposal may require statistical analyses for exploratory outcome measures described in the protocol and/or SAP to be reported. Other commenters indicated that some statistical analyses associated with a primary or secondary outcome measure are considered exploratory, post-hoc, or of sub-groups, rather than primary, and they requested clarification on which of these would be required to be reported. We clarify that the proposal was intended to require the submission of statistical analyses for only primary and secondary outcome measures and, therefore, would not have the effect of requiring statistical analyses for other pre-specified or post-hoc outcome measures (including for sub-groups) not considered primary or secondary outcome measures in the protocol and/or SAP. Similarly, we interpret § 11.48(a)(3)(v) to exclude statistical analyses considered exploratory, even if they are pre-specified in the protocol and/or SAP for primary and secondary outcome measures. In addition, the requirement to submit statistical analyses is limited to those that inform the interpretation of the primary and secondary Outcome Measure Information and Outcome Measure Data that are submitted. Alternatively stated, if the statistical analysis does not rely on data that are specified as primary or secondary outcome measure information in § 11.48(a)(3)(i)–(iv), that analysis does not need to be submitted. For example, if a statistical analysis is requested by FDA for a primary outcome measure based on a different analysis population or is limited to certain sub-groups not summarized in the primary or secondary Outcome Measure Information or Outcome Measure Data, that analysis would generally not meet this requirement. To help the public understand when a reported statistical analysis is pre-specified or post-hoc, the responsible party may voluntarily provide additional information in the accompanying free-text fields as needed to support an understanding of the nature of the analysis.

One commenter suggested that the statistical analysis requirements be applied only to the primary outcome measure(s). Section 402(j)(3)(C)(ii) of the PHS Act requires the submission of "the results of all scientifically appropriate tests of statistical significance of [primary and secondary] outcome measures." However, based on our interpretation of which statistical tests are scientifically appropriate, we are limiting some statistical analysis reporting requirements to primary outcome measures, as described below. Other commenters suggested that scientifically appropriate analyses done in response to an FDA request be limited to the primary outcome measure(s), with one noting that not all FDA-requested analyses are determined to be relevant; another commenter expressed concern that reporting statistical analyses without proper context could be confusing to the public, particularly if analyses requested by FDA were not originally specified in the protocol or analysis plan. This commenter also indicated that clinical trial results presented on *ClinicalTrials.gov* should always be based on the CSR submitted to FDA or other health authorities. For the purposes of results information reporting under the final rule, the results of all scientifically appropriate statistical analyses (as defined in § 11.48(a)(3)(v)) for all pre-specified primary and secondary outcome measures must be reported to *ClinicalTrials.gov.* When these analyses are the same as analyses reported to other regulatory authorities in CSRs, it would be reasonable to use the CSR as the source document for reporting. We further clarify that the requirement for reporting statistical analyses made public by the sponsor or responsible party is limited to analyses of primary outcome measure(s) conducted prior to the date on which clinical trial information about that primary outcome measure is submitted to *ClinicalTrials.gov.* We clarify that the requirement for reporting statistical analyses conducted in response to a request by FDA, which is already limited to analyses of the primary outcome measures, is further limited to those analyses of primary outcome measures for which results information has not yet been submitted to *ClinicalTrials.gov.* That is, primary outcome measures are not required to be updated under § 11.64(a) with statistical analyses conducted in response to a request made by FDA, if such analyses are conducted after clinical trial results information is submitted for the primary outcome measure(s) to which the statistical analysis applies.

In addition, as previously stated, the requirement is limited to statistical analyses that rely on the outcome measure data submitted. We also note that *ClinicalTrials.gov* includes optional free-text fields to allow responsible parties the option to provide additional descriptive information about any submitted statistical analysis, including information regarding why the analysis was done, why it is being reported (*e.g.,* in the case of an FDA-requested analysis), and any limitations of the analysis. This descriptive information should generally not include interpretations of results or conclusions about the analyses because of concerns regarding the introduction of bias discussed in greater detail elsewhere in the preamble. One commenter indicated that statistical analyses requested by FDA may contain confidential commercial information and suggested that the results of statistical analyses should be required to be submitted only when pre-specified in the protocol or SAP. As such, the final rule retains the proposed criteria, with the clarification that statistical analyses conducted in response to a request from FDA are limited to those performed on primary outcome measures. We believe that these criteria identify those statistical analyses that either the responsible party or FDA considers scientifically appropriate. We believe that excluding from the requirement analyses that were prespecified as "exploratory" or that were requested by FDA on outcomes other than the primary outcome measure(s) appropriately balances the reporting burden with the informational benefit.

Several commenters suggested that the proposed structure of, and drop-down choices for, the Statistical Analysis Overview, Statistical Test of Hypothesis, and Method of Estimation elements are too rigid for non-drug/device studies and smaller studies. We note that the scope of this rule is limited to studies of drug products (including biological products) and device products. To help ensure that all required statistical analyses can be fully accommodated, we will provide a general "other" option that can be used to describe and report the results of statistical analyses that cannot be submitted using the options available for Statistical Test of Hypothesis and Method of Estimation. In addition, the list of options for describing the procedure for Statistical Test of Hypothesis and the estimation parameter for Method of Estimation both include an "other" option, and free-text fields are provided for additional explanation, as needed. Commenters suggested that the proposed options for type of statistical test conducted (as part of Statistical Analysis Overview) be expanded from "superiority," "non-inferiority," "equivalence," and "not applicable" to include "estimation" (*e.g.,* rate of events in a given arm) and "descriptive" (*e.g.,* safety analyses). We note that EMA's EudraCT results data bank has a similar data element named "Analysis type" and uses the following list of options: "equivalence," "non-inferiority," "superiority," and "other" [Ref. 98a]. To accommodate these comments and align with EudraCT more closely, we are modifying the list of options for the type of statistical test conducted by replacing "not applicable" with "other" and requiring a description of the type of analysis if the "other" option is selected. One commenter suggested that, based on deficiencies in reporting found in their analysis [Ref. 14], the final rule should require the specification of the non-inferiority or equivalence margin. We note that although this recommendation is consistent with the proposal in section IV.C.4 of the NPRM, the proposed codified provision inadvertently omitted mention of the equivalence analysis. This has been corrected in the final rule. One commenter provided general support for the proposed requirement for Analysis Population Description as part of Analysis Population Information.

We invited comments on whether the list of proposed choices for Measure Type and Measure of Dispersion or Precision was adequate. One commenter requested that "geometric least squares mean" be added to the list of choices. We know from a similar request from a *ClinicalTrials.gov* user that this measure is useful when summarizing data evaluating pharmacokinetics. Based on this comment and our experience, we are adding "geometric least squares mean" to the list of choices for Measure Type in both Demographic and baseline characteristics and Outcomes and statistical analyses. In addition, based on operational experience and routine queries from users, we have identified two other issues with the proposed list of options for Measure Type (*i.e.,* "number," "mean," "median," "least squares mean," "geometric mean," and "log mean." As described in the Comments and Response section for § 11.48(a)(2), we have excluded the "log mean" option from the list of options in the final rule because it is not needed. Second, as also described in this preamble for § 11.48(a)(2), the "number" option is not sufficiently granular to allow for discrimination among different methods of aggregation that use "number" as the Measure Type (such as count of participants or percentage of participants). To address this, we are adding two options to Measure Type to allow responsible parties to specify whether the number is a "count of participants" or a "count of units". We note that this modification more closely aligns the data fields with the EMA's EudraCT results data bank [Ref. 98a], which distinguishes between "countable" and "measurable" types of data. The final rule also updates "Measure Type" to "Measure Type and Measure of Dispersion or Precision" for consistency with the similar data element "Measure Type and Measure of Dispersion" in § 11.48(a)(2)(iii)(B).

We also requested comments on the proposed approach for reporting outcome measure information when (1) a trial is terminated before data are collected for one or more of the pre-specified outcome measures and (2) when outcome measure data are collected but the actual enrollment falls well below the target enrollment. For the first situation, we proposed that the responsible party may specify zero ("0") for the Number of Participants Analyzed and that Outcome Measure Data would not need to be submitted. The responsible party would still be expected to provide the clinical trial results information in proposed § 11.48(a)(1),(2), and (4) (79 FR 69642). For the second situation, we proposed that collected results information for the primary or secondary outcome measure must be submitted but statistical analysis information would not be expected to be submitted because it would not be considered scientifically valid (79 FR 69643). We received comments supporting full reporting of results information for terminated or withdrawn studies. A study with an Overall Recruitment Status of "withdrawn" does not include any enrolled participants and would not require results information submission. We received one comment on the second situation, in which outcome measure data are required to be submitted for a clinical trial in which actual enrollment falls well below the target enrollment. The commenter was concerned about the misinterpretation of such results and suggested that the final rule require the responsible party to provide additional information about the limitations of the data. We note that, in this particular situation, the posted study record would clearly reflect that the trial was terminated (*i.e.,* the responsible party submitted the Overall Recruitment Status as "terminated"), and we intend to include information on the posted study record so that the public can easily see when actual enrollment was below the target enrollment goals (using information from the Enrollment data element and submitted estimated and actual values). We believe that this information will make it easier for the public to consistently identify across studies the specific limitations raised by the commenter, thereby reducing the need to make this a requirement. However, we agree that providing additional information about the limitations of the clinical trial and/or the collected data may be helpful in this and other situations, and we strongly encourage responsible parties to use the related free-text fields and/or the optional Limitations and Caveats data element to provide such information, when appropriate. Additional relevant comments were received in the context of waivers and are addressed in § 11.54, accordingly.

Final Rule

Taking into consideration the comments, our experience operating the *ClinicalTrials.gov* data bank, and the statutory requirements for clinical trial results information, the final rule modifies the proposed approach for Outcome measures and statistical analyses. We clarify in § 11.48(a)(3)(v) that one type of scientifically appropriate statistical analysis is an analysis that is conducted on a primary outcome measure, in response to an FDA request. In the same section, we correct an error that suggested that the submission of statistical analysis information applied only to the information in proposed § 11.48(a)(3)(v)(C). Additional elaboration is also provided on the information required to be submitted as a brief description of each arm/group (a similar omission was described for § 11.48(a)(1) and (a)(2)). We remove the requirement to submit Outcome Measure Reporting Status (see proposed § 11.48(a)(3)(iii)(E)) because a more streamlined approach makes this item obsolete (*i.e.*, the submission of Measure Type and Measure of Dispersion or Precision, Unit of Measure, and Outcome Measure Data are sufficient for determining that Outcome Measure Information and Outcome Measure Data are intended to be posted). We explain how to specify, as part of Outcome Measure Data, whether the number of participants (or units) analyzed in a category differs from the overall Number of Participants Analyzed and Number of Units Analyzed in § 11.48(a)(3)(ii). We have also updated the options available for specifying the type of statistical test in the Statistical Analysis Overview as well as the Measure Type and Measure of Dispersion or Precision (includes additional options for counts of participants or units and for specifying a confidence interval). Finally, minor changes have been made for consistency with similar data items in Demographic and baseline characteristics in § 11.48(a)(2). Final § 11.48(a)(3) otherwise retains the following outcomes and statistical analyses information as proposed: (i) Outcome Measure Arm/Group Information, (ii) Analysis Population Information, (iii) Outcome Measure Information, (iv) Outcome Measure Data, and (v) Statistical Analyses.

As discussed in Section IV.B.4 of this preamble, primary and secondary outcome measures are submitted as part of the registration process. *ClinicalTrials.gov* was designed to display the results of each outcome measure in separate tables organized by arm or comparison group. The responsible party determines the rows and columns for each outcome measure table; columns represent arms or comparison groups, and rows represent data categories (*e.g.*, for categorical data types). The responsible party populates the table cells with data from the clinical trial. Attributes such as measure type (*e.g.*, mean), measure of dispersion or precision (*e.g.*, standard deviation), and unit of measure (*e.g.*, milliseconds) provide context for interpreting the numerical data. In this way, the system can accommodate either continuous or categorical data, as desired by the responsible party based on the design and analysis of the clinical trial as specified in the protocol and SAP. For example, time-to-event data could be provided as either a continuous measure (*e.g.*, median time to response) or as categorical data (*e.g.*, number of participants with response by year 5).

In order to enhance the ability of users to understand and interpret the submitted clinical trial results information and help ensure that submitted information is complete, § 11.48(a)(3)(i)–(v) requires the responsible party to submit information for completing a table of data for each primary and secondary outcome measure, by arm or comparison group, including the results of scientifically appropriate tests of the statistical significance. This is done by submitting the following information, which is used to create and populate the outcome data tables:

(1) Outcome Measure Arm/Group Information, which is described in § 11.48(a)(3)(i) as "[a] brief description of each arm or comparison group used for submitting an outcome measure for the clinical trial, including a descriptive title to identify each arm or comparison group." As discussed in Section IV.C.4 of this preamble on Demographic and baseline characteristics, this information describes the grouping of human subjects for the purposes of analysis, whether by arm of the clinical trial or another comparison group. *ClinicalTrials.gov* will use the Arm Information, Intervention Name, and Intervention Description data elements (submitted as clinical trial registration information), as well as Participant Flow Arm Information and Baseline Characteristics Arm/Group Information, to provide the responsible party with options for pre-populating table column names and descriptions for Outcome Measure Arm/Group Information. The responsible party must review and edit the information as needed to ensure that it appropriately and accurately reflects the outcome measure arms/groups for the clinical trial, or the responsible party may instead define new groups to reflect how outcome measure information was analyzed. As described in the discussion of the term "comparison group" in § 11.10(a) of the preamble, the reference to comparison groups recognizes that when data collected during clinical trials are analyzed, the data are often aggregated into groupings of human subjects (*i.e.*, comparison groups) other than the arms to which the subjects were assigned for the study. It is expected that Outcome Measure Arm/Group Information will be the same as Participant Flow Arm Information, unless human subjects were analyzed in groups different from those to which they were assigned. In this situation, there must be sufficient details for users to understand how the arm(s) or comparison groups used for submitting outcome measures were derived from Participant Flow Arm Information. In general, the Outcome Measure Arm/Group Information must be inclusive of all arms or comparison groups, based on the pre-specified protocol and/or SAP. The Outcome Measure Arm/Group Information must also include sufficient details for users to understand the intervention strategy being described in that arm/group, similar to what is described in this preamble for Participant Flow Arm Information in § 11.48(a)(1).

(2) Analysis Population Information, as described in § 11.48(a)(3)(ii), consists of the following: (A) Number of Participants Analyzed, (B) Number of Units Analyzed, and (C) Analysis Population Description. Number of Participants Analyzed means "[t]he number of human subjects for whom an outcome was measured and analyzed, by arm or comparison group." If the analysis is based on a unit other than participants (*e.g.*, lesions, eyes, implants), the responsible party is also required to provide the Number of Units Analyzed, which is defined as ". . . a description of the unit of analysis and the number of units for which an outcome was measured and analyzed, by arm or comparison group." In addition, if the Number of Participants Analyzed or Number of Units Analyzed in an arm or comparison group differs from the number of human subjects or units assigned to the arm or comparison group, the responsible party is also required to provide an Analysis Population Description, which is explained as "a brief description of the reason(s) for the difference." For example, if some participants assigned to arms drop out before one of the outcome measures is assessed or if some participants are otherwise ineligible for analysis, the responsible party would include an explanation in the Analysis Population Description. Similarly, if a clinical trial enrolled participants but was terminated before outcome measure data were collected, the entry would explain why the Number of Participants Analyzed is zero even though

participants had been assigned to the relevant arm or comparison group.

(3) Outcome Measure Information, as described in § 11.48(a)(3)(iii), includes the following components: (A) Name of the specific outcome measure, including the titles of any categories into which Outcome Measure Data in § 11.48(a)(3)(iv) are aggregated; (B) Description of the metric used to characterize the specific outcome measure; (C) Time point(s) at which the measurement was assessed for the specific metric; (D) Outcome Measure Type, which indicates whether the outcome measure is one of the following types of outcome measures: primary, secondary, other pre-specified, or post-hoc; (E) Measure Type and Measure of Dispersion or Precision, which indicates the type of data submitted and the measure of dispersion or precision; and (F) Unit of Measure (*e.g.,* blood pressure in "millimeters of mercury" or "participants"). As described Section IV.B.4 of this preamble for § 11.28(a)(2)(i)(W) and (X), when an attribute such as blood pressure is summarized using more than one metric or method of aggregation (*e.g.,* mean and median) and/or summarized at more than one time point (*e.g.,* 3 months, 6 months, 9 months), each of these is considered a different outcome measure. In addition, the description of the time point(s) of assessment must be specific to the submitted outcome measure and is generally the specific duration of time over which each human subject is assessed (not the overall duration of the trial). As described in this section of this preamble for Baseline Measure Information, when responsible parties submit information using categories, they may indicate which information type is being reported (participants in mutually exclusive and exhaustive categories or a list of items for which participants may be represented in more than one row) to allow for improved options for data validation (*e.g.,* the system can ensure that the sum of participants in mutually exclusive and exhaustive categories is the same as Number of Participants Analyzed).

In specifying the type of data to be submitted as part of Measure Type and Measure of Dispersion or Precision, the responsible party is required to select one option from the following limited list of options for Measure Type: "count of participants," "count of units," "number," "mean," "median," "least squares mean," "geometric mean," and "geometric least squares mean." In specifying the Measure of Dispersion or Precision, the responsible party is required to select one option from the following limited list of options: "standard deviation," "standard error," "inter-quartile range," "full range," "geometric coefficient of variation" (which is permitted only if the specified Measure Type is "geometric mean" or "geometric least squares mean"), "not applicable" (which is permitted only if the specified Measure Type is "count of participants," "count of units," "number"), "80% confidence interval," "90% confidence interval," "95% confidence interval," "97.5% confidence interval," "99% confidence interval," and "other confidence interval level" (which must also include a specification of the numerical value of the confidence interval level). There is no general "other" option for either the Measure Type or Measure of Dispersion or Precision entries, but responsible parties may optionally provide additional descriptive information as part of the free-text Outcome Measure Description. Collecting Measure Type and Measure of Dispersion or Precision in this format improves the ability of users' to compare submitted information across clinical trials and also ensures complete data submission. For example, if the responsible party indicates that the measure of dispersion is inter-quartile range, *ClinicalTrials.gov* can prompt the submission of the two values corresponding to the upper and lower bounds of the inter-quartile range, instead of only the single value needed to submit a standard deviation. Unit of Measure describes what is quantified by the data (*e.g.,* blood pressure in "millimeters of mercury" or "participants"). Each outcome measure can only have one unit of measure.

In most cases, Name of the specific outcome measure, Description of the metric, Time point(s), and Outcome Measure Type (§ 11.48(a)(3)(iii)(A), (B), (C), and (D)) for the primary and secondary outcome measures would have been submitted at the time of clinical trial registration, as specified in § 11.28(a)(2)(i)(W) and (X), and updated during the course of the clinical trial, as specified in § 11.64. Final § 11.64(a) specifically requires responsible parties to update information submitted during registration at the time they submit results. To ensure consistent data entry and reduce the data entry burden on responsible parties, *ClinicalTrials.gov* will automatically pre-populate the results data tables with the previously submitted (and updated) registration information and will allow the responsible party to make further updates as necessary or desired (*e.g.,* to provide clarification that would enable users to better interpret the submitted results values). If data were not collected for an outcome measure in a clinical trial (*i.e.,* Number of Participants Analyzed in all arms or comparison groups is zero for that outcome measure), the responsible party is not required to submit Measure Type and Measure of Dispersion or Precision and Unit of Measure (§ 11.48(a)(3)(iii)(E) and (F)) for that outcome measure, as no Outcome Measure Data in § 11.48(a)(3)(iv) would be submitted. This situation may occur, for example, if a clinical trial is terminated before data are collected for a pre-specified primary or secondary outcome measure.

(4) Outcome Measure Data, which is described in § 11.48(a)(3)(iv), consists of "[t]he measurement value(s) for each outcome measure for which data are collected, by arm or comparison group and by category (if specified)." The information provided for Outcome Measure Data must use the Unit of Measure and correspond to the Measure Type and Measure of Dispersion or Precision submitted as described in § 11.48(a)(3)(iii)(E) and (F). In addition, the responsible party may specify the number of participants (and units, if applicable), by arm or comparison group, if different in any category from the Number of Participants Analyzed or Number of Units Analyzed in § 11.48(a)(3)(ii)(A) or (B).

(5) Statistical Analyses are specified in § 11.48(a)(v) as the "[r]esults of scientifically appropriate tests of the statistical significance of the primary and secondary outcome measures, if any." In implementing this requirement, we clarify the meaning of "scientifically appropriate" as it relates to Statistical Analyses for the purposes of this regulation only. In this final rule, we specify in § 11.48(a)(3)(v)(A) that a statistical analysis is required to be submitted if it meets any one of the following three criteria in the context of a particular applicable clinical trial:

- A statistical analysis that is pre-specified in the protocol and/or SAP and was performed on primary or secondary outcome measure data. Statistical analyses that are pre-specified in the protocol for a primary or secondary outcome measure, but are considered exploratory, are excluded from these requirements.
- A statistical analysis for a primary or secondary outcome measure that is made public by the sponsor or responsible party, where "made public" is considered to be when the statistical analysis is available in written form (*e.g.,* journal publication, scientific abstract, press release). We believe that the decision by the sponsor or responsible party to publicly disseminate a statistical analysis for a

primary or secondary outcome measure implicitly indicates that an assessment of the scientific appropriateness of the analysis has been made. The fact that the Agency is adopting this approach in the regulation does not reflect the Agency's agreement that such statistical analyses are necessarily scientifically valid. Recognizing that the time at which an analysis is made public and the submission requirements under this rule may not overlap, this criterion is limited to analyses made public before clinical trial results information is submitted for the primary outcome measure(s) studied in the clinical trial.

- A statistical analysis conducted on a primary outcome measure in response to a request made by FDA. We limit the requirement regarding FDA-requested statistical analyses to those analyses requested by FDA for a primary outcome measure prior to the submission of clinical trial results information for all primary outcome measures. This avoids requiring a responsible party to submit FDA-requested analyses if such analyses would be based on results information that was submitted to *ClinicalTrials.gov* prior to FDA's request.

Statistical analyses that meet any of these criteria must be submitted to *ClinicalTrials.gov* at the time of results or partial results information submission. In addition, we clarify that these criteria apply only to statistical analyses that rely on information and data that are specified as primary or secondary outcome measure information in § 11.48(a)(3)(i)–(iv). This limitation is necessary because statistical analyses are only interpretable in the context of the summary outcome measure information that forms the basis for the analysis. These criteria, therefore, do not have the effect of requiring a responsible party to submit primary or secondary outcome measure information in § 11.48(a)(3)(i)–(iv) that is not otherwise required to be submitted.

We specify in § 11.48(a)(3)(v)(B) that the information that a responsible party must submit for statistical analyses of primary and secondary outcome measures is as follows:

(1) Statistical Analysis Overview, which identifies the arms or comparison groups compared in the statistical analysis (by selecting the arms or comparison groups already defined for the outcome measures) and specifies the type of analysis conducted. The type of analysis conducted would be selected from the following limited set of options: "superiority," "non-inferiority," "equivalence," or "other" (which must also include a description of the analysis type). The "other" option would be appropriate for a single group analysis or other descriptive statistics, for example. If the type of analysis selected is "non-inferiority" or "equivalence," the responsible party is also required to provide a free-text description of key parameters of the statistical analysis to include, at minimum, information about the power calculation and the non-inferiority or equivalence margin. An additional comment field is offered to provide the responsible party with the opportunity to submit optional additional information about the statistical analysis.

(2) The Responsible Party must provide either the Statistical Test of Hypothesis or the Method of Estimation, as applicable. If the statistical analysis performed cannot be submitted using the Statistical Test of Hypothesis or Method of Estimation options, a general "other" option is available for submitting any other scientifically appropriate tests of statistical significance. Statistical Test of Hypothesis consists of the p-value and the procedure used for statistical analysis of the outcome data. For convenience in specifying the procedure used for the statistical analysis, *ClinicalTrials.gov* includes the following list of commonly used statistical tests for calculating p-values from which responsible parties may select: "ANCOVA;" "ANOVA;" "Chi-squared;" "Chi-squared, Corrected;" "Cochran-Mantel-Haenszel;" "Fisher Exact;" "Kruskal-Wallis;" "Log Rank;" "Mantel Haenszel;" "McNemar;" "Mixed Models Analysis;" "Regression, Cox;" "Regression, Linear;" "Regression, Logistic;" "Sign Test;" "t-Test, 1-sided;" "t-Test, 2-sided;" and "Wilcoxon (Mann-Whitney)." Responsible parties may also select the "other" option and provide the name of another method. Additional comment fields are available to provide the responsible party with an opportunity to submit optional additional information about the statistical test of hypothesis, such as a description of the null hypothesis, adjustments for multiple comparisons, a priori thresholds for statistical significance, and degrees of freedom. Method of Estimation consists of the estimation parameter, estimated value, and confidence interval (if calculated). For convenience in describing Method of Estimation, *ClinicalTrials.gov* includes the following list of more than a dozen commonly used estimation parameters from which responsible parties may select: "Cox Proportional Hazard;" "Hazard Ratio (HR);" "Hazard Ratio, log;" "Mean Difference (Final Values);" "Mean Difference (Net);" "Median Difference (Final Values);" "Median Difference (Net);" "Odds Ratio (OR);" "Odds Ratio, log;" "Risk Difference (RD);" "Risk Ratio (RR);" "Risk Ratio, log;" and "Slope." Responsible parties may also select the "other" and provide the name of another estimation parameter. If a confidence interval was calculated, the responsible party will submit the confidence level, indicate whether the confidence interval is one-sided or two-sided, and provide the upper and/or lower limits of the confidence interval. A responsible party could specify that the confidence interval is one-sided and provide only the upper or lower limit. If one of the limits of a two-sided confidence interval cannot be calculated, the responsible party is required to specify that limit as "Not Available" and provide a brief narrative explanation (*e.g.,* because an insufficient number of clinical trial participants reached the event at the final time point for assessment). A responsible party may also submit, on an optional basis, a dispersion value. If a dispersion value is submitted, the responsible party is required to specify the parameter of dispersion by selecting one of the following options: "standard deviation" or "standard error of the mean." No "other" option for the parameter of dispersion is available. An additional comment field is available to provide the responsible party with an opportunity to submit optional additional information about the method of estimation, such as the direction of the comparison (*e.g.,* for a relative risk). The requirements for submitting statistical analysis information attempt to balance the benefits of structured data with minimal narrative text with the need to describe what was evaluated in the statistical analysis. For the reasons discussed in section III.C., in addition to the information specified above, responsible parties also have the option of voluntarily submitting additional, free-text information in order to provide a more complete description of the statistical analyses. This free-text information should not include an interpretation of results or conclusions, just a description of the statistical test(s) conducted. Submitted statistical analyses are linked to each submitted outcome measure. Although a responsible party is not limited in the number of statistical analyses that can be submitted for each outcome measure, only statistical analyses that rely on submitted outcome measure information

and data can be described. Specifically, the requirement is limited to statistical analyses that rely on the summary outcome information and data submitted, including Outcome Measure Arm/Group Information, Analysis Population Information, Outcome Measure Information, and Outcome Measure Data. Statistical analyses that use data external to the clinical trial or different analysis populations or are limited to certain sub-groups would generally not meet this requirement unless, for example, the summary sub-group data were submitted as part of the primary or secondary outcome measure (*e.g.*, using categories or comparison groups).

In specifying requirements for outcome measures and statistical analyses under § 11.48(a)(3), two situations merit further clarification. The first involves a clinical trial terminated before data are collected for one or more of the pre-specified outcome measures. Certain information is still required to be submitted for outcome measures for which data were not collected. Under § 11.48(a)(3)(ii) the responsible party would be required to submit the Number of Participants Analyzed, which would be zero ("0") for an outcome measure for which no data were collected. The responsible party is not required to submit the Measure Type and Measure of Dispersion or Precision, and Unit of Measure data elements specified in § 11.48(a)(3)(iii)(E) and (F), for any outcome measure for which data were not collected but would be required to provide the other elements of Outcome Measure Information specified in § 11.48(a)(3)(iii)(A), (B), (C), and (D). As specified in § 11.48(a)(3)(iv), the responsible party is not required to submit Outcome Measure Data for the outcome measure(s) for which no data were collected but is required to submit Outcome Measure Data for any other primary and secondary outcomes for which data were collected. For terminated trials, the responsible party must still meet the requirements specified in § 11.48(a)(1), (2), and (4) for the submission of results information for the Participant Flow, Demographic and baseline characteristics, and Adverse event information modules. If a clinical trial enrolls no participants, the information to be updated for the Enrollment data element under § 11.64(a) would be zero ("0") and no results information would be required to be submitted for that clinical trial.

The second situation involves a clinical trial for which outcome measures are collected but the actual enrollment falls well below the target enrollment. This could occur, for example, if a clinical trial is terminated due to poor enrollment after only some participants are enrolled but outcomes are measured. Even in such situations, collected results information must be submitted to *ClinicalTrials.gov* as specified in this rule (taking into account the privacy considerations discussed in section III.C.16 of the NPRM preamble (79 FR 69591) if actual enrollment is very small). The submission and posting of results information for such a clinical trial would be consistent with section 402(j) of the PHS Act and provide a way of tracking the progress of the clinical trial and demonstrating what happened to the human subjects who were enrolled. If the clinical trial was terminated because of safety concerns or efficacy, the results information would be of considerable interest to users interested in human health and safety information. In order to reduce the chances that users of *ClinicalTrials.gov* might misinterpret submitted results information, we encourage the responsible party to submit additional optional information about the clinical trial in the Analysis Population Description data element and/or in the Limitations and Caveats module of *ClinicalTrials.gov*. This additional information could highlight that enrollment in the clinical trial did not reach the target number of subjects needed to achieve target power and was insufficient to produce statistically reliable results. If the trial was terminated, the posted study record will clearly reflect that the trial was terminated (*i.e.*, the responsible party indicates Overall Recruitment Status as "terminated"), and we intend to include information on the posted study record to allow the public to easily see when actual enrollment was below the target enrollment goals (using information from the Enrollment data element and submitted expected and actual values). We believe that this information will make it easier for the public to consistently identify across studies when a trial was terminated and/or actual enrollment was below the target enrollment goals. We expect that, in most of these situations, no statistical analysis information would be submitted for the affected outcome measure(s) because no statistical analyses would have been performed or would be considered scientifically appropriate.

§ 11.48(a)(4)—Adverse Event Information

Overview of Proposal

The proposal for submitting adverse event information in § 11.48(a)(4) was based on the information required to complete the two tables specified as additional results information in sections 402(j)(3)(I)(iii)(I) and (II) of the PHS Act, with modifications to further assist users in understanding and interpreting submitted adverse event information. Specifically, section 402(j)(3)(I)(i) of the PHS Act requires the Secretary, by regulation, to "determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for applicable clinical trials . . . in a manner and form that is useful and not misleading to patients, physicians, and scientists." Section 402(j)(3)(I)(ii) of the PHS Act specifies that if regulations are not issued by the date that is 24 months after the date of the enactment of FDAAA (*i.e.*, by September 27, 2009), the requirement to submit results information necessary to complete the two tables specified in sections 402(j)(3)(I)(iii)(I) and (II) of the PHS Act would take effect as stated in section 402(j)(3)(I)(ii). The statutorily mandated adverse event reporting provisions require the submission of two tables of information, as follows: (1) "[a] table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial" (section 402(j)(3)(I)(iii)(I) of the PHS Act), referred to hereinafter as the "serious adverse events table" and (2) "[a] table of anticipated and unanticipated adverse events that are not included in the [serious adverse events table] . . . that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial" (section 402(j)(3)(I)(iii)(II) of the PHS Act). In the NPRM and in the *ClinicalTrials.gov* data bank, we refer to adverse events that do not fit the definition of a serious adverse event as "other adverse events," and we refer to the adverse events table in item (2) above as the "other adverse events table" (79 FR 69588).

Consistent with this section of the PHS Act, the Agency proposed in § 11.48(a)(4)(i) to require "[i]nformation for completing two tables summarizing adverse events collected during an applicable clinical trial: (A) Table of all serious adverse events, grouped by organ system, with the number and frequency of each event by arm or comparison group; (B) Table of all adverse events, other than serious adverse events, that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with the number and frequency of each event by arm or comparison group." Proposed § 11.48(a)(4)(ii) further specified that information for each table must include the following: (A) Adverse Event Arm/Comparison Group Information; (B) Total Number Affected by Arm or Comparison Group; (C) Total Number at Risk by Arm or Comparison Group; (D) Total Number Affected by Organ System; (E) Total Number at Risk by Organ System; (F) Adverse Event Information, to include a descriptive term for the adverse event and organ system associated with the adverse event; (G) Adverse Event Data, to include for each adverse event the number of human subjects affected and at risk; and (H) Additional Adverse Event Description. The NPRM also indicated in proposed § 11.48(a)(4)(iii) that information provided by organ system must be grouped using the organ system classification established on *ClinicalTrials.gov.* These data elements (with the exception of the new Total Number Affected by Organ System and Total Number at Risk by Organ System data elements) were first made available in September 2008 as optional data elements; they became required as of September 27, 2009. The Additional Adverse Event Description data element has been available as an optional data element since September 2008 (named Adverse Event Reporting Additional Description) with the following other optional data elements: Time Frame for Adverse Event Reporting, Assessment Type (*i.e.,* collection approach), Source Vocabulary Name (for specifying a standard vocabulary), and Number of Events (for number of occurrences of an adverse event). The NPRM proposal and request for comment on additional data elements was also based on our operational experience with adverse event information since 2008.

In section III.C.15 of the NPRM, we requested comments on all aspects of the proposed requirements for submission of adverse event information. This included considerations of the following: (1) Benefit and burden of the proposed modifications to the statutorily mandated adverse event reporting provisions (*i.e.,* number of participants affected and at risk for adverse events at the organ system level); (2) benefit and burden of additional information considered but not included in the proposal, including the time frame for collecting adverse events, the collection approach (systematic or non-systematic), all-cause mortality information, a standard vocabulary for submitted adverse event terms, number of occurrences of an adverse event and attribution of an adverse event to the intervention(s) under study; (3) ways to reduce the data submission burden without reducing the value of the data; and (4) approaches to increasing standardization in the vocabularies used for adverse event information (79 FR 69591). The Agency also specifically requested comments on whether the organ system classification is sufficient and whether additional categories or an "other" option are necessary (79 FR 69644).

Comments and Response

Most of the commenters who addressed the requirements for adverse event information were generally supportive of the requirements that were consistent with current practice and the statutorily mandated adverse event reporting provisions. Some commenters expressed support for the proposal for adverse event information, including the submission of additional information and the data elements on adverse events on which we sought comment. One commenter expressed overall support for the proposal but generally indicated that it is a change from current practice in academic medical centers and expressed concern about the burden of the requirements. Many commenters addressed issues related to specific data elements and opposed the proposal to require the submission of adverse event information aggregated by the total number of participants affected and at risk for adverse events for each organ system. Commenters expressed opposition to these requirements because they considered the requirements to be beyond the statutorily mandated adverse event reporting provisions and they questioned the Agency's legal authority to require information not specified in those provisions.

We first address the general issue of the Agency's legal authority to require adverse event information not specified in the statutorily mandated adverse event reporting provisions. The adverse event information proposed to be required in § 11.48(a)(4) is based on the provisions in sections 402(j)(3)(I)(iii)(I) and (II) of the PHS Act, with some modifications. We interpret the provision as providing the Secretary with authority to modify the required information, by regulation, under section 402(j)(3)(D)(v)(VI) of the PHS Act, which specifies that the regulations shall establish "additions or modifications to the manner of reporting of the data elements established under [section 402(j)(3)(C) of the PHS Act]." Section 402(j)(3)(I)(v) of the PHS Act deems adverse event information to be "clinical trial information included in [the] data bank pursuant to . . . [section 402(j)(3)(C) of the PHS Act]." We also interpret that this clinical trial information is therefore included in the "data elements established under . . . [section 402(j)(3)(C) of the PHS Act]" referred to in section 402(j)(3)(D)(v)(VI) of the PHS Act. Therefore, we conclude that the Secretary has the authority, under section 402(j)(3)(D)(v)(VI) of the PHS Act, to modify the statutorily mandated adverse event reporting provisions for the submission of adverse event information via regulation, because such modifications represent "additions or modifications to the manner of reporting [adverse event information] . . ."

The modifications to the statutorily mandated adverse event reporting provisions in this final rule represent modifications to the "manner of reporting" required adverse event information. As described above, section 402(j)(3)(D)(v)(VI) of the PHS Act authorizes the Secretary to make "additions or modifications to the manner of reporting of the data elements established under [section 402(j)(3)(C) of the PHS Act]" by regulation. We interpret the "manner of reporting of the data elements" to include specific content requirements for reporting information in the categories of information under section 402(j)(3)(C) of the PHS Act. For example, section 402(j)(3)(C) of the PHS Act identifies certain content requirements for data elements, such as "Primary and Secondary Outcomes." If the "manner of reporting of the data elements established under [section 402(j)(3)(C) of the PHS Act]" does not include the content requirements for these categories, then "additions or modifications" would be strangely limited to changing only how the information must be submitted (*e.g.,* on paper or electronically), not what information must be submitted. This interpretation would leave us in the untenable situation, which we believe was not Congress' intent, of having to limit "additions or modifications" to changes only in *how* information must be submitted, not to *what* information must be submitted. Section 402(j)(3)(I)(i) of the PHS Act also informs this question by directing the Secretary within 18 months to determine by regulation "the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events . . . in a manner and form that is useful and not misleading to patients, physicians, and scientists." Because the "manner" and "form" must be "useful and not misleading," it would not be reasonable to conclude that such regulations could only specify the means of submitting and displaying the adverse event information, but not the information content. Finally, we believe Congress intended the Agency to have broad rulemaking authority to add to the information requirements of the data bank, as demonstrated in section 402(j)(3)(D)(i) of the PHS Act, which directs that the data bank be expanded by rulemaking "[t]o provide more complete results information and to enhance patient access to and understanding of the results of clinical trials." In this section, we explain the modifications made to the statutorily mandated adverse event reporting provisions and clarify how these modifications represent "additions or modifications to the manner of reporting" adverse event information.

Commenters were concerned about the burden of providing adverse event information aggregated by the total number of participants affected and at risk for adverse events for each organ system, particularly for studies at academic medical centers and, in general, because this information is not routinely summarized for adverse events occurring during a trial. Some were concerned about adverse event data being reported differently on *ClinicalTrials.gov* as compared to EMA, FDA labeling, and other summary reports available on the FDA Web site (*e.g.,* 510(k) summary). One commenter was supportive of the proposal only if it meant that all participants affected by an adverse event (whether serious or not) would be summarized by system organ class. Having considered the comments, the Agency is not including a requirement in this final rule to submit the total number of participants affected and at risk for adverse events by organ system. This data element was proposed as a new requirement; it was not part of other adverse event data elements that were implemented in 2009 as optional or required information. The comments helped us understand the extent to which such information is not routinely aggregated in this manner and the potential burdens associated with the requirement. We note that, in general, there will be differences between the information reported on *ClinicalTrials.gov* and in other reports, such as those submitted to FDA, because of differences in the underlying statutory framework and the requirements of the related regulations and elaborations provided in guidance.

There were comments on the proposal to provide adverse event information by system organ class, based on the use of an organ system classification established in *ClinicalTrials.gov.* Most of these comments were in the context of the proposed requirement to summarize the total number of participants affected and at risk for adverse events for each organ system, which is not included in the final rule. The NPRM preamble described this organ system classification as based on the Medical Dictionary for Regulatory Affairs (MedDRA) [Ref. 99] (79 FR 69589) As a standardized medical terminology, MedDRA is used internationally for the reporting of drug and biologic regulatory information and was adopted by ICH [Ref. 100]. Commenters indicated that at academic institutions there are not institution-wide systems established for the collection of adverse event information in a standard manner that would include MedDRA's organ system classification and that investigator-sponsors may not have access to MedDRA. In addition, commenters indicated that the requirements should be kept simple and "consistent with current practice." One commenter requested an extended transition period for ongoing studies to allow for the incorporation of MedDRA into their processes. Some commenters also requested implementation of a new PRS feature to assist investigators who are responsible parties in classifying adverse events using MedDRA system organ classes. Although the final rule no longer includes the proposal to require the total number of participants affected and at risk by organ system, there is still a requirement to provide, for each adverse event, the "[o]rgan system associated with the adverse event."

The proposal to require this organ system information is derived from the statutorily mandated adverse event reporting provisions that specified that adverse events need to be "grouped by organ system." The organ system classification used to describe a specific adverse event submitted to *ClinicalTrials.gov* has been based on MedDRA organ system classes since the adverse events module was made available in September 2008 (and was required in September 2009). Thus, the final rule is consistent with current practice. Our experience indicates that responsible parties are able to use these classes effectively and that a single set of organ system classes provides a consistent way to display information about adverse events among the tables for a single trial and across trials. We also note that there are publicly available resources for mapping to MedDRA system organ classes, such as the NCI's thesaurus [Ref. 101], "a widely recognized standard for biomedical coding and reference, used by a broad variety of public and private partners both nationally and internationally including the Clinical Data Interchange Standards Consortium Terminology (CDISC), the U.S. Food and Drug Administration (FDA), the Federal Medication Terminologies (FMT), and the National Council for Prescription Drug Programs (NCPDP)." In the final rule, to clarify the circumstances in which the organ system is relevant, we have removed the general provision from the codified that stated that the information "must be grouped according to the organ system classification established in *ClinicalTrials.gov.*" Instead, when submitting the organ system associated with the adverse event, as specified in final § 11.48(a)(4)(iii)(D)(2), the responsible party is required to select one option describing the organ system from a list of options established on *ClinicalTrials.gov.* This approach improves consistency with other data elements in which the format (also described in Section IV.A.4) is to select from menu options. The use of this particular list for organ system class is based on our experience with voluntary and mandatory adverse events submission since September 2008, which indicates that responsible parties are able to use these classes effectively and that a single set of organ system classes provides a consistent way to display information about adverse events among the tables for a single trial and across trials.

Two commenters indicated that, for certain trials of devices, the protocol specifies adverse event reporting only for organ systems that may be affected by the device. We note that we do not intend for these regulations to result in requiring an investigator to collect adverse event information of any type or in any way that is not specified in the protocol. Therefore, if adverse events were collected for only some organ systems, as pre-specified in the protocol, the responsible party would need to submit only those adverse events to *ClinicalTrials.gov.* The Additional Adverse Events Description data element (renamed "Adverse Event

Reporting Description" in the final rule) could be used to describe the methods for adverse event collection, including any organ system classes that were not evaluated. We also note that since the publication of the NPRM, MedDRA version 19.0 was released, which includes a new system organ class called "product issues." We will add this to the classification on *ClinicalTrials.gov*, bringing the total number of organ system classes to 27. Although we requested comments on whether an "other" option is necessary for the organ system class, no specific comments were received.

Commenters requested that instead of the proposed requirement to report other adverse events that exceed a frequency of 5 percent within any arm of the clinical trial, the final rule require all other adverse events to be reported (*i.e.*, other adverse events that exceed a frequency of 0 percent). These commenters were concerned that the 5 percent threshold for reporting other adverse events did not have a clear scientific basis and potentially would allow some findings to go unreported. Similarly, one commenter requested that "all adverse events occurring in five percent or more of patients across arms receiving the investigational product" be required to be reported, based on a concern that if there are multiple arms with the investigational product, the overall frequency of adverse events among participants receiving the investigational product may be higher than 5 percent. Another commenter suggested that the 5 percent threshold could be used for differentiating expected and unexpected adverse events. Our proposal for reporting anticipated and unanticipated other adverse events that exceed a frequency of 5 percent within any arm of the trial is based on section 402(j)(3)(I)(iii)(II) of the PHS Act. As stated in the NPRM (79 FR 69588), we will allow the submission of other adverse events with a frequency of 5 percent or less on an optional basis, as many responsible parties are currently doing. This allows responsible parties to determine whether a threshold of 5 percent or less is scientifically appropriate for their study. We believe that this approach strikes an appropriate balance between the potential burden of reporting all adverse events for all applicable clinical trials and the scientific value of allowing responsible parties to report adverse events occurring below the 5 percent threshold for a particular clinical trial. If a responsible party chooses to report adverse events that occur at a lower frequency (*i.e.*, 5 percent or less), the specific threshold must be identified (*e.g.*, 3 percent) and used for reporting all adverse events in each arm of the trial. This approach helps avoid the type of reporting bias that occurs when the reporting threshold varies by adverse event or by arm. Similarly, not permitting the threshold to be higher than 5 percent, which is consistent with section 402(j)(3)(I)(iii)(II) of the PHS Act, avoids another type of reporting bias that could occur if the threshold was allowed to be set at any value (*i.e.*, higher thresholds in some trials but not others could exclude the submission of important adverse event information). Therefore, we maintain the approach described in the NPRM to require the reporting of all other adverse events, other than serious adverse events, that exceed a frequency of 5 percent within any arm of the clinical trial.

We invited comments on the benefits and burdens of requiring additional adverse event information, including time frame, collection approach, all-cause mortality information, and a standard vocabulary for adverse event terms (79 FR 69590). Some commenters were in favor of adding a requirement to submit the adverse event reporting time frame; one reason given was that the provision of this information would help avoid inappropriate comparisons across clinical trials that used different time frames. We agree that the time frame is important for comparing information across trials, and we note that it is also important for interpreting clinical trial results information within the context of a single trial, since the time frames for data collection for primary outcome measures, secondary outcome measures, and adverse events may all be different. Similarly, we note that § 11.44(d) describes partial results information submission deadlines based on when final data collection occurs for primary outcome measures, secondary outcome measures, and additional adverse event information. In this context, it is particularly important to have a description of the adverse event reporting time frame so that it is clear what time frame for assessment applies to adverse event information submitted as partial results. In the NPRM, we noted that responsible parties provided time frame information for more than half of the results information submitted in 2012 for probable applicable clinical trials (79 FR 69590). (See the explanation of probable applicable clinical trial in section IV.B.2). In 2015, nearly 60 percent of results submitted for probable applicable clinical trials included information for the time frame data element. Based on the current use of this data element and the implications for interpreting adverse event information in the context of a single clinical trial and across trials, we are adding adverse event reporting time frame as a requirement in the final rule. As explained in detail earlier in this section, we consider this required information to represent a modification to the "manner of reporting" in section 402(j)(3)(D)(v)(VI) of the PHS Act; the information helps elucidate the adverse event information in the statutorily mandated reporting provisions.

Commenters who addressed the issue of collection approach for adverse event information were generally in favor of adding a requirement to submit this information, suggesting that such contextual information is important for interpreting the benefits and harms of an intervention evaluated in a trial and for comparing adverse event information across trials. Collection approach information includes an indication of the type of approach taken to collect adverse event information, either a systematic assessment or a non-systematic assessment. In the NPRM, we explained that a "systematic assessment" involves the use of a specific method of ascertaining the presence of an adverse event (*e.g.*, the use of checklists, questionnaires,specific laboratory tests at regular intervals), and a "non-systematic assessment" relies on the spontaneous reporting of adverse events, such as unprompted self-reporting by participants (79 FR 69590). [Ref. 102] One commenter suggested that the information be provided in a free-text field (instead of as a binary indication) to allow the responsible party to describe how adverse events were collected and adjudicated. We acknowledge that this can be a complex issue; however, we believe that the binary, structured indication of either a systematic or non-systematic assessment provides users of *ClinicalTrials.gov* with a consistent way of understanding what was done in the clinical trial. We also note that the free-text field for Adverse Event Reporting Description can be used by the responsible party to describe the methods for adverse event collection and provide any further details about adjudication. The submission of the protocol, as described in § 11.48(a)(5), also would typically provide additional supporting information that is important for interpreting the collection approach and the submitted adverse event information. Another commenter requested clarification "on the classification of routine investigator assessment of adverse events (when an investigator asks if the subject has had an adverse event) as a Systematic Assessment." We interpret this routine investigator assessment to mean that the investigator asks a general question about whether a participant had any adverse events at prespecified intervals, rather than more targeted questions about specific categories or types of adverse events. We clarify that such a routine, general assessment would be considered a "non-systematic assessment." However, if more specific questions were asked about adverse events at regular intervals, this approach could be considered a "systematic assessment." We agree with the commenters that knowledge of the collection approach affects comparability of information across clinical trials and we believe that such information is similarly important for interpreting adverse event information for a single clinical trial. As we noted in the NPRM, clinical trials using non-systematic assessment approaches typically record fewer adverse events than those using a systematic assessment approach [Ref. 102]. We also noted in the NPRM that, of the results for probable applicable clinical trials submitted to *ClinicalTrials.gov* in 2012, 76 percent voluntarily included information about the approach to collecting adverse events (79 FR 69590). In 2015, reporting was about the same, with 74 percent of results submitted for probable applicable clinical trials including information on the collection approach for adverse events. Based on the current use of this data element and the importance of this information for interpreting adverse event information, we require this information in the final rule. As explained in detail earlier in this section, this required information constitutes a modification to the "manner of reporting" in section 402(j)(3)(D)(v)(VI) of the PHS Act; this information helps elucidate the adverse event information in the statutorily mandated adverse event reporting provisions.

Commenters who addressed the topic of including all-cause mortality information supported requiring the submission of such information, with the exception of one commenter. Commenters who supported the requirement stated that accurate information about the number of deaths in each arm of the clinical trial was critical for interpreting the trial's results. One of these commenters suggested that it would be misleading to have a statement specific to all-cause mortality information that explains that deaths may not be related to the intervention evaluated because this is actually what randomized trials are designed to understand. In addition, if there were such a statement, it would apply equally to other results, including outcomes. Some commenters (including some who supported the requirement) expressed concern about the interpretation of all-cause mortality information, particularly in the absence of information about attribution (*i.e.,* whether the deaths were considered related to the intervention). The commenter opposed to the requirement expressed concern that the reporting of all-cause mortality information would increase the risk of re-identification of participants in the clinical trial, leading to requests for waivers of the clinical trial results information submission requirements, but the commenter did not provide further explanation of how the risk of re-identification would increase.

We have considered these comments and require in the final rule the submission of all-cause mortality information in addition to the serious adverse events and other adverse events tables. This required information constitutes a modification to the "manner of reporting" in section 402(j)(3)(D)(v)(VI) of the PHS Act; this information helps elucidate the adverse event information in the statutorily mandated adverse event reporting provisions. Specifically, although other clinical trial results information may include information about deaths, the total number of deaths that occurred during the clinical trial might not be readily apparent (*e.g.,* submitted serious adverse event information indicates the number of subjects who experienced a myocardial infarction, but it would not necessarily indicate how many of the subjects died from the event).

As noted in the NPRM, submission of all-cause mortality information would be consistent with other clinical trial reporting guidelines (79 FR 69590) [Ref. 56, 103]. The all-cause mortality information is described in § 11.48(a)(4)(ii) of the final rule as being provided by the responsible party in a separate table. This approach allows the responsible party to use the Adverse Event Arm/Group Information as the table columns and, for each arm/group (*i.e.,* separate column), to specify the overall number of human subjects affected by death due to any cause and the overall number of human subjects included in the assessment as a table row. The information will then be displayed as a row in the serious adverse events table in the posted study record. As with serious and other adverse event information, we will make available an optional data element for providing descriptive information that the responsible party deems appropriate.

We acknowledge the concerns expressed by some of the commenters about potential misinterpretation of adverse event information. To address those concerns, we intend to provide standard explanatory information on each posted record that will help the public understand the definition of "all-cause mortality" and that will further explain that all-cause mortality information, serious adverse events, and other adverse events appearing on *ClinicalTrials.gov* are generally reported regardless of attribution. Similarly, in the context of all results information, a standard statement on the posted record will indicate that results of a single clinical trial may not be representative of the overall efficacy and safety profile of the product and that the FDA-approved product labeling should be consulted for information for approved drug products (including biological products) and device products. In response to the comment about waivers, we note that the NPRM indicated that a high risk of re-identification would be an appropriate reason for requesting that the requirement for submitting all-cause mortality information be waived, using the process described in proposed § 11.54. However, because adverse event information is summary data provided in aggregate, we expect that waivers would be requested and granted in a very limited number of situations.

Comments were mixed on the issue of whether attribution of an adverse event to a specific intervention evaluated in a study should be provided. Some commenters were opposed to providing information about attribution because of a lack of consensus about the optimal methodology for making such determinations, leading to concerns about the potential for tremendous variability and subjectivity across clinical trials regarding how decisions about attribution were made. Commenters indicated that attribution can only be assessed after a trial is completed (*e.g.,* by comparing rates of events across arms of the clinical trial), and even then, decisions about attribution based on a single clinical trial may be incorrect. Similarly, one of these commenters cited FDA guidance to reviewers that instructs them to "discount" attribution information [Ref. 104]. One commenter suggested that because of the challenges in correctly assigning attribution, such information should be prohibited. One commenter suggested that a disclaimer be added to adverse event information to explain that the data do not necessarily reflect a conclusion by the sponsor or FDA that the event was caused or contributed to by the intervention. Some commenters were in favor of the submission of attribution information because they thought it was necessary to prevent misunderstandings about the safety of study interventions, including devices, and the risks of trial participation. One commenter indicated that the requirements for adverse event submission should be limited to only those serious adverse events and adverse events considered related to the intervention. In addition to the concerns raised by the commenters, we note that providing information on attribution would add an additional burden on responsible parties. Given the challenges described by commenters in accurately assigning attribution within the context of a single clinical trial, as well as similar concerns that we raised in the NPRM (79 FR 69589), we are not including attribution information in the final rule. We recognize that the monitoring of adverse events during a clinical trial has an important role in identifying the risks and benefits for human subjects participating in the clinical trial. [Ref. 105]. Attempts to determine attribution of an intervention to each individual adverse event, however, may be subjective (and potentially misleading), particularly after study completion when aggregate adverse event information is available to make objective quantitative assessments of the potential attribution of the intervention to the adverse event. [Ref. 106, 107, 108]. As noted in the discussion for all-cause mortality, we intend to include a standard statement on *ClinicalTrials.gov* to help the public understand that all-cause mortality information, serious adverse events, and other adverse events are generally reported regardless of attribution. We received one comment in support of requiring the submission of the number of occurrences of an adverse event (in addition to the number of participants affected by the adverse event). This optional data element has been available to responsible parties since the adverse events module was released in September 2008, and we will continue to make it available as an optional data element.

A few commenters addressed the topic of whether we should require the submission of adverse event terms using a standard vocabulary. One of the commenters was opposed, citing in particular the burden that would be imposed if that particular vocabulary had not been used in a trial from the outset. Another commenter recommended that a standard vocabulary for adverse events be used, noting that emerging technologies could potentially take advantage of standard terminologies. We also interpret many of the comments received on using the MedDRA classification system for summarizing the total number of participants affected and at risk for adverse events by organ system as opposition to requiring a specific vocabulary. We did not receive any other suggested approaches for standardizing the vocabularies used for adverse event information. Taking into consideration the burden and the potential for this requirement to cause a responsible party to report or collect adverse event information in any way that is not specified in the protocol, we do not include in the final rule a requirement to submit adverse event terms using a standard vocabulary. We will, however, continue to provide optional data elements to allow responsible parties to describe the standard vocabulary that was used, if applicable.

We also received some comments in response to our request for additional input on ways to reduce the data submission burden without reducing the value of the data. Commenters requested tools (in addition to XML) for uploading datasets for the adverse event tables. In the preamble of this final rule describing the format required for submitting clinical trial information in § 11.8, we note that the PRS has allowed the submission of adverse event information in a spreadsheet format (*e.g.,* Microsoft Excel) since 2013. We will continue to support uploading of adverse event information that uses this format and meets the technical specifications.

Some commenters suggested that the regulations explicitly state that only adverse event information collected "per protocol" is required to be submitted. The requirements in the final rule are not intended to cause an investigator to collect information of a type or in a way not specified in the protocol. However, situations may arise during the conduct of a trial in which the responsible party collects and reports certain relevant adverse events that were not anticipated in the protocol and/or that occur in participants thus not following the protocol. Therefore, we maintain the proposed language in the final rule (*i.e.,* "collected during") to cover all relevant situations. But we reiterate that the requirements in the final rule do not impose data collection requirements for an applicable clinical trial. One commenter suggested that adverse event information requirements should be less rigorous for products not being conducted under an IND/IDE because the safety and efficacy has already been established. We do not agree that the reporting of adverse event information for clinical trials not being conducted under an IND/IDE should be less rigorous. We believe that the purpose of the *ClinicalTrials.gov* database to make information available to the public is best achieved by requiring the same adverse event reporting requirements for all applicable clinical trials.

Final Rule

Final § 11.48(a)(4) generally maintains the NPRM approach, but we are making the following changes in the final rule: First, we remove the proposed requirement that the overall number of participants affected and at risk, by arm or comparison group, be reported by organ system class. Second, we add a requirement to submit all-cause mortality information by arm or comparison group. Third, we add a requirement to provide the time frame for adverse event data collection. Fourth, we add a requirement to provide the collection approach (systematic or non-systematic) for adverse events. In addition, in developing the final rule we have identified a few issues that would benefit from further clarification, based on our operational experience and routine queries from users. Specifically, we are clarifying the additional information required to be provided including a brief description of each arm/group (a similar omission was described for § 11.48(a)(1), (2), and (3)). We have renamed the proposed Additional Adverse Event Description data element to "Adverse Event Reporting Description" and included it as § 11.48(4)(i)(B) with the other requirements added in the final rule (*i.e.,* Time Frame and Collection Approach) that also pertain to information about methods for adverse event collection. In addition, this name change is intended to reduce the potential for misinterpreting the data element as relating to a specific adverse event, rather than to definitions related to adverse event reporting overall. The change also better aligns the name of this data element with the optional data element in place on *ClinicalTrials.gov* prior to the final rule.[Ref. 97]. In addition, minor changes have been made for consistency with terms used in the statute and with similar data items in Demographic and baseline characteristics specified in § 11.48(a)(2) and Outcomes and statistical analyses in § 11.48(a)(3).

Final § 11.48(a)(4) requires the submission of summary information on anticipated and unanticipated adverse events that occurred during an applicable clinical trial. This includes a table of all serious adverse events; a table of adverse events other than serious adverse events that exceed a frequency of 5 percent within any arm of the clinical trial; and a table of all-cause mortality information, which will be displayed as a row in the serious adverse event table. Such information is considered part of results information. The requirements derive from the statutorily mandated adverse event reporting provisions in sections 402(j)(3)(I)(ii)–(iii) of the PHS Act and include the following additional requirements intended to assist users in understanding and interpreting the submitted adverse event information: Arm/group description, adverse event reporting description, time frame, collection approach, and all-cause mortality information.

We interpret modifications to the "manner of reporting" in section 402(j)(3)(d)(v)(VI) of the PHS Act to include, among other things, information that helps elucidate the adverse event information required by the statutorily mandated adverse event reporting provisions. The definitions of "adverse event" and "serious adverse event" are provided in § 11.10(a).

Final § 11.48(a)(4)(i) requires the responsible party to submit information that describes the methods for collecting adverse event information. The Time Frame data element, as specified in § 11.48(a)(i)(A), describes the time period over which the submitted adverse event information was collected as well the overall period of time for which additional adverse event information was, is being, or will be collected (*e.g.,* primary outcome measure data and adverse events collected over the same time period as the primary outcome are submitted, but secondary outcome measure and additional adverse event data collection is ongoing). Similar to the information provided for outcome measures on the time points of assessment (§ 11.48(a)(3)(iii)(C)), the time frame for adverse event reporting is generally the specific duration of time over which each human subject is assessed for adverse events. Time frame information is a "manner of reporting" adverse event information and helps elucidate the adverse event information required by the statutorily mandated adverse event reporting provisions.

In cases in which the protocol specifies the collection of only a limited set of adverse events (*e.g.,* unanticipated adverse reactions), the responsible party is still required to submit three tables of information that summarize the information collected during the clinical trial with respect to serious adverse events, other adverse events (other than serious adverse events) that exceed a frequency of 5 percent within any arm of the trial, and all-cause mortality. The all-cause mortality information will be displayed as a row in the serious adverse event table. As specified in § 11.48(a)(4)(i)(B), if the adverse event information collected in the trial is collected based on a definition of "adverse event" and/or "serious adverse event" that is different from the definitions in § 11.10(a), the responsible party must use the Adverse Event Reporting Description data element to explain the differences. Similarly, the responsible party must use the Adverse Event Reporting Description data element to explain whether these definitional differences include adverse event collection methods that exclude certain types of adverse events required to be reported in § 11.48(a)(4) (*e.g.,* protocol specified that other adverse events are not to be collected, only serious adverse events are collected). This explanation facilitates the understanding of required adverse event information in situations where different definitions or methods of collection are used. Adverse Event Reporting Description constitutes a "manner of reporting" adverse event information that facilitates understanding the nature of the events being reported. Responsible parties may also use the Adverse Event Reporting Description data element, on an optional basis, to provide general information that they deem important for explaining methods of adverse event collection and reporting, including additional details about the collection approach.

Collection Approach, specified in § 11.48(a)(i)(C), allows the responsible party to identify whether a "systematic assessment" or "non-systematic assessment" approach was taken to collect adverse event information during the trial. Responsible parties must specify the assessment type for adverse event information as a whole or for each adverse event in each table. Systematic assessment involves the use of a specific method of ascertaining the presence of an adverse event (*e.g.,* the use of checklists, questionnaires, or specific laboratory tests at regular intervals). Non-systematic assessment relies on spontaneous reporting of adverse events, such as unprompted self-reporting by participants. This information explains how the statutorily mandated adverse event information was obtained and constitutes a "manner of reporting" this information authorized to be required by section 402(j)(3)(D)(v)(VI) of the PHS Act. We note that the requirements are not intended to cause an investigator to collect adverse event information of any type or in any way not specified in the protocol.

Final § 11.48(a)(4)(ii) specifies that responsible parties must submit three tables summarizing information on all serious adverse events, other adverse events with a frequency higher than 5 percent in any arm or comparison group of the clinical trial, and all-cause mortality. Final § 11.48(a)(4)(iii) specifies that there must be a description of each arm or comparison group for which adverse event information was collected and the overall number of human subjects affected by and at risk must be described for each of the following tables: (1) Serious adverse events, (2) adverse events other than serious adverse events that exceed a frequency threshold of 5 percent within any arm, and (3) deaths due to any cause. We note that the death of a human subject could be reflected in information included in the serious adverse event table and in the all-cause mortality table. For example, a death separately identified in the serious adverse event table with a descriptive term for the adverse event such as "myocardial infarction" (as specified § 11.48(a)(4)(iii)(D)(1)) would also be included in the overall number of human subjects affected in the all-cause mortality table. The all-cause mortality information required by this rule is simply another meaningful way to aggregate and report one important type of serious adverse event (*i.e.,* those that led to death). The all-cause mortality information is a "manner of reporting" the adverse event information authorized to be required by section 402(j)(3)(D)(v)(VI) of the PHS Act.

The arm and comparison group information is provided once by the responsible party and is used for all three tables. As similarly discussed in this section under Demographic and baseline characteristics and Outcomes and statistical analyses, the Adverse Event Arm/Group Information data element describes the grouping of human subjects for the purposes of summarizing adverse event information. These descriptions are necessary to understand the statutorily mandated adverse event reporting information. Adverse Event Arm/Group Information is another "manner of reporting" the adverse event information authorized to be required by section 402(j)(3)(D)(v)(IV) of the PHS Act. *ClinicalTrials.gov* will use the Arm Information, Intervention Name, and Intervention Description data elements (submitted as clinical trial registration information), as well as Participant Flow Arm Information, Baseline Characteristics Arm/Group Information, and Outcome Measure Arm/Group Information, to provide the responsible party with options for pre-populating table column names and descriptions for Adverse Event Arm/Group Information. The responsible party must review and edit the information as needed to ensure that it appropriately and accurately reflects the adverse event arms/groups for the clinical trial, or the responsible party may instead define new groups to reflect how adverse event information was analyzed. As described in the discussion of the term "comparison group" in § 11.10(a) of the preamble, the reference to comparison group recognizes that when data collected during clinical trials are analyzed, the data are often aggregated into groupings of human subjects (*i.e.,* comparison groups) other than the arms to which the subjects were assigned for the study. It is expected that Adverse Event Arm/Group Information will be the same as Participant Flow Arm Information, unless human subjects were analyzed in groups that are different from those to which they were assigned. In this situation, there must be sufficient detail to understand how the arm(s) or comparison groups used for submitting adverse events were derived from Participant Flow Arm Information. In general, Adverse Event Arm/Group Information must be inclusive of all arms or comparison groups, based on the pre-specified protocol and/or SAP. Adverse Event Arm/Group Information must also include sufficient details to understand the intervention strategy being described for that arm/group, similar to that which is described in § 11.48(a)(1) for Participant Flow Arm Information.

For each of the serious and other adverse events tables described in § 11.48(a)(4)(ii)(A) and (B), respectively, the responsible party must provide a descriptive term for each serious adverse event and other adverse event with a frequency higher than 5 percent in any arm of the clinical trial (§ 11.48(a)(4)(iii)(D)(*1*)), along with the organ system that is associated with the adverse event (§ 11.48(a)(4)(iii)(D)(*2*)), number of participants experiencing the adverse event (§ 11.48(a)(4)(iii)(E)(*1*)), and number of participants at risk for the adverse event (§ 11.48(a)(4)(iii)(E)(*2*)). In most cases, the number of participants at risk for the adverse event will equal the number of participants who started that arm of the clinical trial. However, the number of participants at risk could differ if, for example, participants were assigned to an arm but did not receive the intervention (*e.g.,* because they dropped out of the clinical trial) or because a comparison group combines participants from multiple arms of the trial. The number of participants at risk for each adverse event will generally be the same as the overall number of participants at risk in the arm or comparison group. To minimize the burden of data entry, the overall number of participants at risk will be pre-populated for each adverse event term. However, if these numbers are not the same (*e.g.,* certain adverse events were only systematically evaluated in a sub-group of human subjects enrolled in the clinical trial), the responsible party can modify the number of participants at risk for each adverse event, as needed. Using the data submitted for the number of participants that experienced the adverse event and the number of participants at risk, *ClinicalTrials.gov* will automatically calculate the frequency (percentage of participants who experienced the event). This approach helps reduce calculation errors and helps users interpret the frequency information in those cases in which the full study population may not have been at risk for a specific adverse event or when the number of participants at risk is different across comparison groups.

Adverse events described in § 11.48(a)(4)(iii)(D)(*1*) must be submitted with an indication of the organ system associated with the adverse event (as described in § 11.48(a)(4)(iii)(D)(*2*)) using the classification scheme specified on *ClinicalTrials.gov,* which includes the following 27 items adapted from the MedDRA version 19.0: Blood and lymphatic system disorders; Cardiac disorders; Congenital, familial and genetic disorders; Ear and labyrinth disorders; Endocrine disorders; Eye disorders; Gastrointestinal disorders; General disorders; Hepatobiliary disorders; Immune system disorders; Infections and infestations; Injury, poisoning and procedural complications; Investigations; Metabolism and nutrition disorders; Musculoskeletal and connective tissue disorders; Neoplasms benign, malignant and unspecified (including cysts and polyps); Nervous system disorders; Pregnancy, puerperium and perinatal conditions; Product issues; Psychiatric disorders; Renal and urinary disorders; Reproductive system and breast disorders; Respiratory, thoracic and mediastinal disorders; Skin and subcutaneous tissue disorders; Social circumstances; Surgical and medical procedures; and Vascular disorders organ classes [Ref. 99]. No "other" option is included. "Product issues" is not an organ class (like most of the other categories), but this term is used in MedDRA for issues with "product quality, devices, product manufacturing and quality systems, supply and distribution, and counterfeit products" [Ref. 109]. "Social circumstances" is also not an organ class but is used in MedDRA to accommodate the classification of some types of adverse events that are not specific to an organ system, such as an automobile accident, a homicide, or a fall. Adverse events that affect multiple systems must be reported only once (to avoid over-counting), preferably under the organ system class that is considered primary. If there is no primary organ system class, the event should be listed under "General disorders," and additional information may be provided in the optional free-text field, Adverse Event Term Additional Description.

Finally, we note that the Agency interprets section 402(j)(3)(I)(v) of the PHS Act to deem the adverse event information required under section 402(j)(3)(I) of the PHS Act as clinical trial results information not only for all applicable clinical trials but also for all voluntarily-submitted clinical trials under section 402(j)(4)(A) of the PHS Act. Therefore, responsible parties who submit clinical trial information subject to section 402(j)(4)(A) of the PHS Act must submit adverse event information in accordance with § 11.48(a)(4). Additional information on the clinical trial information requirements for voluntarily-submitted clinical trials under section 402(j)(4)(A) of the PHS Act, is described in Section IV.D.1.

§ 11.48(a)(5)—Protocol and Statistical Analysis Plan

Section 11.48(a)(5) adds a requirement to submit the protocol and statistical analysis plan as part of clinical trial results information. The proposal, comments and response, and final rule requirements are discussed in detail in Section III.D.

§ 11.48(a)(6)—Administrative Information

Overview of Proposal

Proposed § 11.48(a)(5)(i) implemented section 402(j)(3)(C)(iii) of the PHS Act, which requires that "a point of contact for scientific information about the clinical trial results" be submitted as part of clinical trial results information, and specified the submission of the following information to allow users of *ClinicalTrials.gov* to inquire about the results of a clinical trial: (1) Name or official title of the point of contact, (2) name of affiliated organization, and (3) telephone number and email address of the point of contact (79 FR 69644). This proposal reflects the Results Point of Contact data element used on *ClinicalTrials.gov* since the results database was first launched in September 2008 [Ref. 97].

Proposed § 11.48(a)(5)(ii) implemented section 402(j)(3)(C)(iv) of the PHS Act, which requires responsible parties to indicate "whether there exists an agreement . . . between the sponsor or its agent and the principal investigator . . . that restricts in any manner the ability of the principal investigator, after the primary completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial." The statutory provision also provides that this requirement does not apply to an agreement between a sponsor or its agent and the principal investigator solely to comply with applicable provisions of law protecting the privacy of participants in the clinical trial. We explained in the proposed rule preamble that in accordance with proposed § 11.48(a)(5)(ii), we required responsible parties to indicate (yes/no) whether the principal investigator is an employee of the sponsor. If the principal investigator is an employee of the sponsor (yes), no further information must be provided, although it may be provided voluntarily. If the principal investigator is not (no), the responsible party would be required to indicate (yes/no) whether an agreement (other than one solely to comply with applicable provisions of law protecting the privacy of human subjects participating in the clinical trial) exists between the sponsor or its agent and the principal investigator that restricts in any manner the ability of the principal investigator, after the primary completion date of the clinical trial, to discuss the results of the clinical trial at a scientific meeting or any other public or private forum or to publish in a scientific or academic journal information concerning the results of the clinical trial. We also proposed to permit responsible parties to provide additional optional information about existing agreements. The proposal reflected the Certain Agreements data element used on *ClinicalTrials.gov* since the results component of the database was first launched in September 2008 [Ref. 97]. We invited public comment on the proposed approach, on any experience to date with the current approach, and on other information that might be collected on a voluntary basis (*e.g.*, types of principal investigator disclosure restrictions) (79 FR 69644).

Comments and Response

Regarding the results point of contact in proposed § 11.48(a)(5)(i), a few commenters suggested that the final rule not require the submission and posting of information that would identify an individual employee. One commenter proposed to instead require a general facility email address or contact form. We generally agree with these comments and note that the proposed approach, which is retained in the final rule, did not require the disclosure of an individual's name or specific contact information, but permitted the use of an official title and a general organizational phone number or email address. While the name of a specific individual and contact information for that individual are not required, a responsible party must provide sufficient information to allow users to reach a contact able to provide additional scientific information about the clinical trial results found on a posted record.

Some commenters addressed the certain agreements provision in proposed § 11.48(a)(5)(ii). One commenter suggested the addition of another category to the existing three optional choices currently available on *ClinicalTrials.gov,* to help viewers understand restrictions related to multi-site trials. For example, a sponsor may limit or prohibit individual-site principal investigators from disclosing single-site results before the overall results aggregated from all sites of a multi-center trial are disclosed. Another commenter proposed that such agreements be nullified in the event that clinical trial information submitted by a sponsor without the consent or knowledge of the principal investigator is found to be misrepresented or in the event of any legal proceedings arising from false or misleading data. In response to the first commenter, the Agency will consider the suggestion when deciding in the future whether to modify or restructure the optional principal investigator Disclosure Restriction Type component of the Certain Agreements data element. In response to the second commenter, the legal status of agreements between a sponsor or its agent and the principal investigator is outside the scope of this rulemaking. Final § 11.48(a)(6)(ii) provides the mechanism for mandatory reporting of the existence of such agreements for applicable clinical trials under this part.

Final Rule

Taking into consideration the commenters' suggestions and the statutory requirements for the submission of additional components of clinical trial results information, the final rule maintains the approach proposed in § 11.48(a)(5). Final § 11.48(a)(6)(i) requires the submission of the following information for a point of contact for scientific information about the results information for a clinical trial: Name or official title, name of the affiliated organization, and the telephone number and email address. We note that point of contact information is required to be submitted even if it is the same as the information for the responsible party, because we do not plan to make public the responsible party's contact information.

Final § 11.48(a)(6)(ii) requires the submission of information about certain agreements between the principal investigator and the sponsor. The responsible party must indicate whether the principal investigator is an employee of the sponsor. If the principal investigator is not an employee, the responsible party must indicate whether any agreement exists that restricts the principal investigator from disclosing the results of the clinical trial after the primary completion date. Consistent with the definition of "principal investigator" in § 11.10, we interpret this provision as applying to a principal investigator who has oversight of the entire applicable clinical trial, not to site-specific investigators or other investigators (such as those on grant-funded studies) who may be referred to as principal investigators in other contexts but who do not meet the definition of "principal investigator" under this part. We clarify that when the responsible party for a clinical trial is a sponsor-investigator, for the purposes of submitting information about certain agreements in § 11.48(a)(6)(ii), we interpret that the sponsor-investigator is both the sponsor and the principal investigator and is therefore considered an employee of the sponsor for the purposes of this section. We also clarify that the information about certain agreements that is required to be submitted under this regulation must accurately represent the status at the time of initial results information submission, and if that information has changed since the previous submission of partial clinical trial results information, the responsible party must submit information to reflect the new status of certain agreements between the principal investigator and the sponsor at the time of the subsequent submission of partial results information, in accordance with § 11.44(d)(3)(ii). For example, if the principal investigator had been an employee of the sponsor prior to results information submission but is no longer employed by the sponsor at the time of initial results information submission, the principal investigator would not be considered an employee of the sponsor for the purposes of submitting partial results information about certain agreements. However, if the principal investigator's employment status subsequently changes and he or she becomes an employee of the sponsor prior to the submission of final results information, the certain agreements information would need to be included when submitting partial results information as specified in § 11.44(d)(3)(ii). Note that the Certain Agreements results data element specified in § 11.48(a)(6)(ii) is excluded from the update requirements specified in § 11.64(a)(2).

Additionally, in our interactions with responsible parties and consultations with stakeholders, we have learned that certain agreements of the nature described in section 402(j)(3)(C)(iv) of the PHS Act are routine in the clinical trials community, although they may vary in their terms and the duration of their limitations on the principal investigator. Such agreements, as we understand them, typically permit the sponsor or its delegate to review results communications prior to public release and impose a short-term embargo of 60 days or less, from the date that the communication is submitted to the sponsor for review, although other agreements may impose restrictions that are much longer in duration or broader in scope [Ref. 110]. In order to allow responsible parties to provide additional information about the agreements in place between the sponsor or its delegate and the principal investigator, we permit the submission of optional, structured information about the agreement. These optional data elements, which are separate and distinct from the two data elements required as part of clinical trial results information, as previously discussed, are: (1) Whether the principal investigator is an employee of the sponsor and, if not, (2) whether any agreement exists that restricts the principal investigator from discussing or publishing the results of the clinical trial after the primary completion date. Thus, currently on *ClinicalTrials.gov,* a responsible party who wishes to provide this additional information may choose from among the following:

(1) The only disclosure restriction on the principal investigator is that the sponsor can review results communications prior to public release and can embargo communications regarding clinical trial results for a period that is less than or equal to 60 days from the date that the communication is submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot unilaterally extend the embargo.

(2) The only disclosure restriction on the principal investigator is that the sponsor can review results communications prior to public release and can embargo communications regarding clinical trial results for a period that is more than 60 days but less than or equal to 180 days from the date that the communication is submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot unilaterally extend the embargo.

(3) Other disclosure agreement that restricts the right of the principal investigator to disclose, discuss or publish clinical trial results after the trial is completed. The responsible party may provide an additional description of the disclosure agreement.

Based on our experience operating *ClinicalTrials.gov,* the usage of these optional responses suggests that they provide an acceptable way to describe these agreements in a consistent format. These categories of optional information may be modified over time to reflect information that we learn about changes in clinical trials practice or to provide other information of interest to users. As permitted by law, we may make these changes without notice and comment rulemaking. However, we will provide prior notice and seek public comment on any proposed changes of a substantive nature to the format of required results information submission information (see § 11.8 and the discussion in Section IV.A.4 of this preamble).

§ 11.48(a)(7)—Additional Clinical Trial Results Information for Applicable Device Clinical Trials of Unapproved or Uncleared Device Products

Overview of Proposal

Proposed § 11.48(a)(6)(i) enumerated additional descriptive information that responsible parties would need to submit as part of the clinical trial results information for applicable device clinical trials of unapproved or uncleared devices for display on the posted record. For applicable device clinical trials of unapproved or uncleared devices subject to delayed posting of registration information in proposed § 11.35(b)(2)(i), the results information specified in proposed § 11.48(a)(1) through (5) can be submitted as specified in proposed § 11.44(c) and publicly posted as required by proposed § 11.52 *prior* to the date on which clinical trial registration information is publicly posted (79 FR 69645).

In proposing § 11.48(a)(6)(i), we exercised the authority granted under sections 402(j)(3)(D)(ii)(II) and 402(j)(3)(D)(iii) of the PHS Act to require responsible parties of applicable device clinical trials of unapproved or uncleared devices to submit, as part of results information, certain additional descriptive information that is similar to the type of information submitted at the time of registration. In particular, section 402(j)(3)(D)(ii)(II) of the PHS Act authorizes the Secretary to determine through rulemaking whether responsible parties for applicable clinical trials of unapproved products would be subject to the results information submission requirements under proposed subpart C. Additionally, section 402(j)(3)(D)(iii)(IV) of the PHS Act grants the Secretary wide discretion in determining what information can be required through rulemaking to be submitted as part of results information, stating that the regulations "shall require, in addition to the elements described in [section 402(j)(3)(C)] . . . [s]uch other categories as the Secretary determines appropriate." Therefore, the Secretary can require, through rulemaking, submission of not only the results information required under section 402(j)(3)(C) of the PHS Act, but also "such other categories" of information as the Secretary determines appropriate. We noted in the NPRM that we interpret "such other categories" of results information for applicable device clinical trials of unapproved or uncleared device products to include, among other things, certain descriptive information that is similar to the type of information required to be submitted under section 402(j)(2)(A)(ii) of the PHS Act. We pointed out that if clinical trial registration information is not available until after the posting of results information, users of *ClinicalTrials.gov* would lack access to certain descriptive information necessary to enhance access to and understanding of, the submitted results information and to determine whether the required results information has been submitted (*e.g.,* for all arms of the study). Therefore, this descriptive information, as a component of clinical trial results information for unapproved or uncleared devices, would be posted based on the timeline specified in § 11.52 (79 FR 69645).

To make submission of the necessary descriptive information easier and to reduce the risk of inconsistency or error, § 11.48(a)(6)(ii) proposed to require responsible parties to affirm the accuracy of the descriptive information that is similar to the type of information submitted when the trial is registered by verifying and updating it as necessary and then affirming that this descriptive information is ready to be posted with the results information. Once affirmed, the proposed rule explained, *ClinicalTrials.gov* would automatically populate the clinical trial results descriptive information data elements using the previously submitted clinical trial registration elements that are similar to the type of information to be submitted when the trial is registered. The proposed approach would decrease the burden on responsible parties, reduce inconsistencies between information previously submitted at registration and information submitted with results, and increase administrative efficiency by reducing the need for the Agency to conduct a wholly-new quality control review of the submitted information (79 FR 69645).

Comments and Response

We did not receive any specific comments about the proposal to require additional descriptive results information for applicable device clinical trials of unapproved or uncleared devices in proposed § 11.48(a)(6). We did receive comments concerning the submission of any results information for unapproved or uncleared devices, and these comments are addressed in Section III.B. of this preamble.

Final Rule

Final § 11.48(a)(7)(i) specifies the additional results information necessary to enhance access to and understanding of the results of applicable clinical trials of unapproved or uncleared device products consistent with the proposed rule. However, this section clarifies that this requirement is limited to applicable clinical trials of unapproved or uncleared device products for which clinical trial registration information has not been posted publicly by the Director on *ClinicalTrials.gov* in accordance with § 11.35(b)(2)(i). This section also includes minor modifications to the names of data elements for consistency with modifications to the data elements in § 11.10(b). Additionally, final § 11.48(a)(7) clarifies that "device" means "device product."

Final § 11.48(a)(7)(ii) states that responsible parties must submit all the results information specified in § 11.48(a)(7)(i). We clarify that this applies to all applicable device clinical trials of unapproved or uncleared device products that are subject to § 11.48(a)(7)(i), regardless of when the trial was initiated. We also clarify that if a responsible party indicates to the Director that it is authorizing the Director, in accordance with § 11.35(b)(2)(ii), to publicly post its clinical trial registration information on *ClinicalTrials.gov* prior to the date of FDA approval or clearance of the device product, the applicable device clinical trial of its unapproved or uncleared device product is not subject to § 11.48(a)(7)(i).

Section 11.48(a)(7)(ii) additionally requires responsible parties to submit an affirmation that any information previously submitted to *ClinicalTrials.gov* for the data elements listed in paragraph § 11.48(a)(7)(i) of this section have been updated in accordance with § 11.64(a) and are to be included as clinical trial results information. As described above, to make submission of the necessary descriptive information under § 11.48(a)(7)(i) easier and to reduce the risk of inconsistency or error, *ClinicalTrials.gov* will automatically populate the clinical trial results descriptive information data elements using the previously submitted clinical trial registration elements that are similar to the type of information submitted when the trial is registered. This automatic population approach is intended to decrease the burden on responsible parties, reduce inconsistencies between information previously submitted and information submitted with results, and increase administrative efficiency. The affirmation in § 11.48(a)(7)(ii) therefore applies to the previously submitted information that will be used to populate the data elements listed in § 11.48(a)(7)(i). The responsible party must enter any additional descriptive information that has not been automatically populated, as § 11.48(a)(7)(ii) requires the submission of all results information specified in § 11.48(a)(7)(i).

§ 11.48(b)—Results Information for a Pediatric Postmarket Surveillance of a Device Product That Is Not a Clinical Trial

Overview of Proposal

Proposed § 11.48(b) specified the results information that must be submitted to *ClinicalTrials.gov* for a pediatric postmarket surveillance of a device that is not a clinical trial. We proposed that the final report submitted to FDA according to 21 CFR 822.38 (or any successor regulation) must be submitted to *ClinicalTrials.gov* in a common electronic document format and must include redactions of personally identifiable information and commercial confidential information. We invited public comment on the proposed approach (79 FR 69646).

Comments and Response

Commenters addressed the proposal for a pediatric postmarket surveillance of a device that is not a clinical trial in proposed § 11.48(b). Commenters recommended that the final rule alternatively allow for the submission of a study summary in place of a redacted final report, suggesting that the redacted final report "might be confusing and virtually unreadable." One commenter indicated that a pediatric postmarket surveillance of a device that is not a clinical trial should be required to provide the same clinical trial results information (as for a clinical trial) identified in proposed § 11.48(a). As noted in the NPRM, "pediatric postmarket surveillances under section 522 of the FD&C Act can take various forms [other than a clinical trial], including a detailed review of the complaint history and the scientific literature, non-clinical testing, observational studies . . ." (79 FR 69576). As such, it may not always be possible or appropriate for the responsible party for a pediatric postmarket surveillance of a device that is not a clinical trial to provide all of the specified results data elements or data tables required for clinical trials in proposed § 11.48(a). Regarding the suggested submission of a study summary, it is not clear, based on the comments, which specific items would be included in such a summary and how the components could be described in the context of this final rule. Because of the broad spectrum of types of studies that may be considered pediatric postmarket surveillances of a device, it is not possible to fully elucidate the items that should be present in such a summary that would apply to all types of studies. On the other hand, the final report submitted to FDA would include the results information that was deemed important by FDA. Therefore, we maintain the approach in the final rule that the responsible party is required to provide a copy of the final report submitted to FDA. This approach ensures that the information and requirements are consistent for all types of pediatric postmarket surveillances of a device product that are not clinical trials. We have, however, modified the requirement as described in the NPRM, in that we are not requiring that the final report be redacted. Upon further consideration, we believe that it is appropriate to leave decisions about information to be redacted to the discretion of the responsible party.

Final Rule

Taking into consideration the commenters' suggestions and the statutory requirements for the submission of clinical trial results information for a pediatric postmarket surveillance of a device that is not a clinical trial, we maintain in the final rule the approach proposed in § 11.48(b), but we remove the requirement to redact information from the final report submitted to FDA and clarify that "device" means "device product."

Final § 11.48(b) specifies the results information that must be submitted to *ClinicalTrials.gov* for a pediatric postmarket surveillance of a device product that is not a clinical trial. We recognize that a pediatric postmarket surveillance of a device product may take any of several forms, including prospective surveillance studies and historical reviews of the health records of those who have received a device as an intervention, and may not meet the definition of a "clinical trial" under this part. For this reason, it is not possible to specify particular data elements or tables of data for all types of pediatric postmarket surveillances of a device product that are not clinical trials. For each pediatric postmarket surveillance of a device product that is not a clinical trial, the final report submitted to FDA according to 21 CFR 822.38 (or any successor regulation) is required to be submitted to *ClinicalTrials.gov*. The responsible party may redact names, addresses, and other personally identifiable information, as well as any proprietary information (*i.e.*, trade secrets and/or confidential commercial information) contained in the report, but the redacted information should not include any of the information required to be submitted under §§ 11.28(a) or 11.48(a) of this part. The final report is required to be submitted in a common electronic document format specified on *ClinicalTrials.gov* at *https://prsinfo.clinicaltrials.gov* (or successor site).

5. § 11.52—By when will the NIH Director post submitted clinical trial results information?

Overview of Statutory Provisions and Proposal

According to section 402(j)(3)(G) of the PHS Act, for applicable clinical trials, the Director of NIH is required to post results information "publicly in the registry and results database not later than 30 days after such submission." Proposed § 11.52 implemented this provision, stating that NIH will post publicly "clinical trial results information submitted under this subpart at *ClinicalTrials.gov* not later than 30 calendar days after the date of submission" (79 FR 69646).

Comments and Response

The comments received on the provisions specified in § 11.52 for posting of clinical trial results information pertained to the proposed quality control procedures (described in section III.C.12 of the NPRM and proposed § 11.66) and the timing of posting in relationship to those procedures. These comments are addressed in full in Section IV.D.3 of this preamble which addresses the requirements for corrections in § 11.64(b)(1) (which now includes the provisions proposed in § 11.66). We describe here the comments specific to the timeline for posting. Some commenters supported the proposal for posting, however, a number of commenters favored the quality control review of information and suggested that information on both registration and results should be posted only after quality control review process has concluded. Commenters expressed concern about the potential to misinform those using the public record and suggested only posting sections that have fulfilled quality control criteria. Some commenters suggested that the harm of posting information before the quality control review process has concluded is greater than the benefit of posting the information in a timely manner. While we understand these concerns, we interpret the statutory posting deadline to be a clearly delineated timeline between submission and posting. In addition, in the event that a study record is posted in accordance with the statutory posting deadline and the quality control review process has not concluded, the clinical trial record will contain information that will be visible to those viewing the record on *ClinicalTrials.gov* to make it clear that the quality control review process has not concluded for the posted clinical trial information.

Final Rule

Taking into consideration the commenters' concerns and the statutory requirements for posting clinical trial results information, we maintain the NPRM proposal in the final rule. For clarity, we have modified the title of § 11.52 such that it is now "By when will the NIH Director post submitted clinical trial results information?" As discussed further in the preamble for § 11.10, we clarified that clinical trial results information means the data elements the responsible party is required to submit to *ClinicalTrials.gov* as specified in the PHS Act or as specified in these regulations, as applicable. Thus, we have clarified § 11.52 by removing the phrase "submitted under this subpart." We have also clarified that the requirement does not apply to information submitted under section 402(j)(4)(A) of the PHS Act and § 11.60.

Section 11.52 applies only to clinical trial results information required to be submitted to *ClinicalTrials.gov*. Reflecting section 402(j)(2)(C) of the PHS Act, as codified in § 11.42, clinical trial results information is required to be submitted for certain applicable clinical trials "for which clinical trial registration information is required to be submitted" (see § 11.42(a) and (b)). Section 11.22 specifies which applicable clinical trials must be registered. For such trials that voluntarily register with *ClinicalTrials.gov*, regardless of whether they are subject to the requirements for voluntary submission under § 11.60 or are subject to the requirements in § 11.60(a)(2)(ii), we intend to post results information as soon as practicable after clinical trial results information has been submitted and after the issues identified during quality control are corrected or adequately addressed.

6. § 11.54—What are the procedures for requesting and obtaining a waiver of the requirements for clinical trial results information submission?

Overview of Proposal

Section 402(j)(3)(H) of the PHS Act provides that "[t]he Secretary may waive any applicable requirements of this paragraph [(3) of the PHS Act] for an applicable clinical trial, upon written request from the responsible party, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is consistent with the protection of public health or in the interest of national security . . .'' The statute also stipulates that if such a waiver is granted, the Secretary will notify the appropriate congressional committees that the waiver has been granted and explain why it has been granted, not later than 30 calendar days after the waiver has been granted. Proposed § 11.54 implemented this provision by outlining procedures by which a responsible party may submit a written request for a waiver from the requirements of subpart C for an applicable clinical trial. Proposed § 11.54(a) specified the details for the submission and content of the waiver request, including that the request identify the specific requirement(s) for which the waiver is requested. Proposed § 11.54(b) specified the procedures and deadlines for appealing a denied waiver request, and § 11.54(c) provided that the Director would include a notation in the clinical trial record for the waived results submission requirement and that the Secretary would notify the appropriate congressional committees of the waiver and why it was granted (79 FR 69646).

The proposed rule noted that we expected that waivers would be requested and granted in only a very limited number of situations, and we described an example of a situation in which a waiver might be granted, namely if results information could be submitted only in a manner that would likely enable the re-identification of clinical trial participants. We invited public comments on other situations in which a waiver might be granted and would be consistent with the protection of public health or in the interest of national security. With regard to the notation on the clinical trial record, we explained that it was intended to inform users of *ClinicalTrials.gov* that the absence of certain results information does not constitute a failure to comply with the statute and implementing regulation. We also explained that because the waiver would be based on extraordinary circumstances that could include considerations of public health and/or national security, we proposed that we would not publicly post information describing the reason for the waiver. We invited public comment on this proposal as well (79 FR 69646).

Comments and Response

Several commenters addressed the Agency's proposed procedures for handling waiver requests. Commenters suggested additional examples of situations that they thought would warrant a waiver of the results information submission requirements. Several commenters suggested that a waiver was warranted when the principal investigator could no longer serve as the responsible party such as when the investigator relocates or in the event of their death or disability. Commenters suggested that a waiver would relieve the institution of the burden of having to fulfill the responsible party's obligations to submit results information. We do not consider a principal investigator's inability to fulfill their responsibilities as an extraordinary circumstance that would satisfy the statutory standard. Section 11.4(c)(3) provides for the reassignment of the responsible party function when the principal investigator no longer meets or is no longer able to meet all of the requirements for designation as the responsible party or in the event of the principal investigator's death or incapacity. Other comments emphasized the importance of maintaining flexibility in the process of considering requests for waivers for results information reporting and asserted that without flexibility in the system, waiver requests may be unnecessarily denied. We believe that the proposed rule provides the necessary mechanisms and the flexibility for considering waivers while also protecting public health and national security.

Comments were also received suggesting that the proposed rule's 15 calendar day deadline for data submission following waiver denial or appeal denial should be extended, including a proposal to allow the waiver request to be submitted 60 calendar days before the results information submission deadline, allowing the Secretary 30 calendar days to transmit a decision and an additional 60 calendar days for an appeal resolution. We agree with the comments that longer timeframes are appropriate and have included 30-calendar day deadlines in the final rule.

Commenters also supported the use of justified waiver requests as well as a publicly posted notation on the clinical trial record if results information submission is waived. Other commenters suggested making the waiver request and appeal public and allowing the public to appeal a reason given in a waiver request by a responsible party. Since the waiver would be based on extraordinary circumstances that could include considerations of public health and/or national security, the Agency will retain the proposed approach of not posting information describing the reason for the waiver.

Final Rule

Taking into consideration the public comments and the statutory requirements set forth in section 402(j)(3)(H) of the PHS Act, the final rule retains the proposed rule with the exception of the timeframes for submitting results information after a waiver denial, for appealing a waiver denial, and for submitting results information after a denial of the waiver on appeal. These timeframes have been extended from 15 calendar days to 30 calendar days. The final rule also clarifies in § 11.54(d) that for an applicable clinical trial with a primary completion date before the effective date of the rule, the responsible party may submit a waiver request as specified in section 402(j)(3)(H) of the PHS Act. This is consistent with the differing requirements that apply to applicable clinical trials, depending on the primary completion date of the applicable clinical trial, as discussed further in Section IV.F of this preamble. Section 11.54 of the rule outlines procedures by which a responsible party may submit a request for a waiver from any or all requirements of results information submission. We expect that waivers will be requested and granted only for extraordinary circumstances that could include the need to protect the public health and/or the interests of national security. The Agency will issue guidance on how to submit such waiver requests.

Section 11.54(a) of the rule specifies that waiver requests must be submitted by the responsible party to the Secretary or a delegated official in the format specified at *https://prsinfo.clinicaltrials.gov/* (or successor site) and indicate the NCT number, Brief Title, and Name of the Sponsor of the applicable clinical trial. This information is necessary to ensure accurate identification of the specific trial for which the waiver is requested (*i.e.,* the combination of NCT number and Brief Title will assist in identifying mistyped NCT numbers) and the key parties involved (*i.e.,* sponsor and responsible party). Since the statute grants the Secretary the authority to waive ''any applicable requirements'' for the submission of results information if justified by ''extraordinary circumstances,'' the rule requires the responsible party to identify the specific provisions(s) for which a waiver is requested and provide a description of the extraordinary circumstances that are believed to justify the waiver. The responsible party will not be required to comply with the results information submission provisions in subpart C for which the waiver is granted. Such provisions could include all or just some of the provisions for which the waiver is requested. The responsible party will continue to be required to comply with any remaining provisions of subpart C for which the waiver is not requested or not granted. It is important to note, however, that a responsible party may still need to provide certain information in the PRS to indicate that the results information submission requirement was waived for that information. After a waiver is granted, the Agency will work with the responsible party to address the specific requirements that are waived. In some cases, for example, the responsible party may need to enter "0 participants" with an explanation that a waiver was provided for such information. While a waiver request is pending, the responsible party will not be required to submit other required clinical trial results information. The deadline for submitting results information to *ClinicalTrials.gov* is the later of the original submission deadline or 30 calendar days after a notification denying the waiver is sent to the responsible party.

Section 11.54(b) details the process by which a responsible party may appeal a denied waiver request to the Secretary or delegated official and indicates that additional information about the format of the appeal will be specified at *https://prsinfo.clinicaltrials.gov/* (or successor site). If this responsibility is delegated to a Department or Agency official, the delegated official will, as a matter of practice, differ from the delegated official for reviewing the initial waiver request. As with the original request, the responsible party is not required to comply with specific provisions of subpart C for which the waiver is granted upon appeal. For the provisions for which a waiver is not granted upon appeal, the responsible party is required to submit results information by the later of the original results information submission deadline or 30 calendar days after the notification denying the appeal is sent to the responsible party. Of note, we have replaced the word "transmitted," used in the proposed rule, with the phrase "sent to the responsible party" in final § 11.54(b)(1) and added the phrase "to the responsible party" in final § 11.54(b)(3). Although these changes do not alter the meaning of these provisions, we believe they further clarify that the responsible party has 30 calendar days from the date the notification is sent from the Agency as evidenced by the date stamp on the notification.

Section 11.54(c)(1) requires the Director to include a notation in the clinical trial record that specified elements of the results information submission requirements have been waived. This notation is intended to inform users of *ClinicalTrials.gov* that the absence of certain results information does not necessarily constitute a failure to comply with the statute and implementing regulation. Section 11.54(c)(2) implements section 402(j)(3)(H) of the PHS Act by requiring the Secretary, if a waiver is granted, to notify the appropriate congressional committees that the waiver has been granted and explain why it has been granted, not later than 30 calendar days after any part of the waiver is granted. Since the waiver would be based on extraordinary circumstances that could include considerations of public health and/or national security, the Agency will not post publicly information describing the reason for the waiver.

Section 11.54(d), as described above, states that a responsible party for an applicable clinical trial with a primary completion date before the effective date of the rule may request a waiver from any of the applicable requirement(s) for clinical trial results information submission in accordance with the procedures specified in section 402(j)(3)(H) of the PHS Act.

D. Subpart D—Additional Submissions of Clinical Trial Information

1. § 11.60—What requirements apply to the voluntary submission of clinical trial information for clinical trials of FDA-regulated drug products (including biological products) and device products?

Overview of Proposal

Proposed § 11.60 described requirements that would apply to voluntary submissions of information for certain clinical trials not otherwise subject to the registration and results information submission requirements of section 402(j) of the PHS Act. Section 402(j)(4)(A) of the PHS Act specified that "[a] responsible party for a clinical trial that is not an applicable clinical trial, or that is an applicable clinical trial that is not subject to paragraph (2)(C), may submit complete clinical trial information described in paragraph (2) or paragraph (3) [of the PHS Act] provided the responsible party submits clinical trial information for each applicable clinical trial that is required to be submitted under section 351 [of the PHS Act] or under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial." Based on this provision, the proposed rule described two types of clinical trials of FDA-regulated drugs or devices for which submission of information is not otherwise required: (1) Clinical trials that do not meet the definition of an applicable clinical trial; and, (2) clinical trials that are applicable clinical trials but are not required to register under proposed section § 11.22(a) (*i.e.,* clinical trials that are applicable clinical trials that were initiated on or before September 27, 2007, and that reached their completion dates before December 26, 2007) (79 FR 69647).

Under proposed § 11.60, if a responsible party voluntarily submitted clinical trial information for either type of clinical trial for which submission of information is not otherwise required, the responsible party would be required to submit registration information as specified in proposed § 11.60(a)(2)(i)(A) or results information as specified in proposed § 11.60(a)(2)(i)(B) for the voluntarily submitted clinical trial. In addition, proposed § 11.60(a)(2)(ii) and § 11.60(a)(2)(iii) described additional applicable clinical trials (*i.e.,* "triggered" trials) for which clinical trial information would be required to be submitted if a responsible party voluntarily submitted clinical trial information for a clinical trial not otherwise required to be registered. In this context, "triggered" trials referred to "each applicable clinical trial that is required to be submitted under section 351 [of the PHS Act] or under section 505, 510(k), 515, or 520(m) of the [FD&C] Act in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial" as specified in section 402(j)(4)(A) of the PHS Act. Requiring the submission of information for "triggered" trials helps prevent selective voluntary submissions of results information from clinical trials that only show positive results for a particular product, but not from those applicable clinical trials that show negative or uncertain results for the same product (79 FR 69648). Additionally, proposed § 11.60(a)(2)(iv) provided deadlines applying to voluntary submissions and proposed § 11.60(a)(2)(v) specified that all voluntary submissions would be subject to the update and corrections requirements proposed in §§ 11.64 and 11.66, respectively. Finally, proposed § 11.60(b) provided a statement to accompany applicable clinical trial information that was submitted voluntarily as specified in section 402(j)(3)(D)(v)(V) of the PHS Act (79 FR 69649).

Comments and Response

Several commenters addressed proposed § 11.60. Some commenters supported the proposed requirements, while one suggested that the scope of the mandatory submission requirements should be modified to encompass all trials covered by the proposed voluntary submissions requirements, including those of currently marketed drugs and devices completed before the enactment of FDAAA. The Agency appreciates these comments and the underlying sentiment for broad trial registration and results information reporting policies. We note that responsible parties have always been able to submit voluntarily the registration and/or results information for clinical trials of currently marketed drugs and devices that were completed before the enactment of FDAAA. We also note that § 11.60 of the final rule provides that, as of September 27, 2007, responsible parties who make such voluntary submissions and are manufacturers of the studied product must also submit clinical trial information for all "triggered" applicable clinical trials required to be provided to FDA in a marketing application or premarket notification, in order to avoid selective disclosure of information about a product on *ClinicalTrials.gov.*

Other commenters suggested that the Agency consider including fewer requirements in the final rule to encourage more voluntary submissions, while another requested the removal of proposed requirements for updating and correcting voluntarily submitted trial information because of concerns that such a burden may have the unintended consequence of discouraging voluntary submissions. In response, the Agency has reviewed proposed § 11.60(a) and determined that each requirement is necessary to ensure that voluntary submissions would be provided in accordance with the statute. Further, we have added the Study Completion Date data element, as defined in § 11.10 of the final rule and discussed in Section IV.A.5 of this preamble, to the list of required additional results data elements that must be provided when the responsible party voluntarily submits clinical trial results information for a clinical trial for which the clinical trial registration information specified in § 11.60(b)(2)(i)(B), and 11.60(c)(2)(i)(B) have not been submitted. The Study Completion Date is needed to identify that the requirements for voluntary partial results information submission in § 11.60(a)(2)(iv)(A), 11.60(b)(2)(iv)(A), and 11.60(c)(2)(iv)(A), and obligations for updates and corrections in §§ 11.60(c)(2)(v) and 11.64 have been fulfilled. That is, even though a responsible party for a trial may need to submit partial results information several times voluntarily in order to meet different deadlines (*i.e.,* because of different dates for final data collection for primary and/or secondary outcome measures or for the pre-specified time frame for collecting adverse events), that responsible party's obligation for voluntary results information submission is only completely fulfilled after all required results information is submitted not later than 1 year following the Study Completion Date. With regard to the updating and correction requirements in proposed § 11.60, section 402(j)(4)(A) of the PHS Act provides that voluntary submissions of information must consist of "complete" clinical trial registration and/or results information. The updating requirements help ensure that any subsequent changes in clinical trial information for a voluntarily submitted trial (*e.g.,* overall recruitment status) are reflected in the data bank. Additionally, the error correction requirements provide for the timely revision of submitted clinical trial information. As with mandatory submissions, these requirements are intended to help assure that all voluntary submissions are complete and accurate.

A commenter expressed concerns over a statement to accompany applicable clinical trials submitted voluntarily in proposed § 11.60(b). The commenter suggested that submitted statements may be written in language too technical for the public to understand and recommended several approaches to clarifying the meaning, such as providing a hyperlink to a page containing an explanation written in non-technical language or amending the statement directly with non-technical language. The Agency agrees that the proposed language was too technical and has modified the statement in the final rule by adding a non-technical first sentence and placing the original technical statement in parenthesis for clarity: "This clinical trial information was submitted voluntarily under the applicable law and, therefore, certain submission deadlines may not apply. (That is, clinical trial information for this applicable clinical trial was submitted under section 402(j)(4)(A) of the Public Health Service Act and 42 CFR 11.60 and is not subject to the deadlines established by sections 402(j)(2) and (3) of the Public Health Service Act or 42 CFR 11.24 and 11.44.)"

In addition, a few commenters requested clarification on additional issues. In particular, one commenter requested clarification of the word "triggered" as used in the preamble section of the proposed rule. In the preamble of the proposed rule and this final rule, we use the term "triggered" to refer to the statutory requirement that a responsible party who has voluntarily submitted clinical trial information for a clinical trial that is not an applicable clinical trial or that is an applicable clinical trial that is not subject to the registration requirements, and who is the manufacturer of the FDA-regulated drug product (including a biological product) or device product being studied, must also submit clinical trial information for each applicable clinical trial required to be submitted to FDA in a marketing application or premarket notification for approval, licensure, or clearance of the drug product (including a biological product) or device product for the use studied in the voluntarily submitted trial. However, the term "triggered" is not used in the regulatory text of the final rule in § 11.60.

Another commenter expressed concern that proposed § 11.60 could be used for the voluntary submission of clinical trial information for studies of unproven stem cell and cell based therapy interventions to *ClinicalTrials.gov* as "phase 1" trials for promoting medical tourism and other activities. The comment further suggested that the Agency consider additional requirements for voluntary submissions in the final rule, such as review of the approval status for each submitted intervention by the relevant competent authorities. The Agency appreciates these comments and the underlying sentiment for trial registration and results reporting information. Nevertheless, allowing voluntary submissions for clinical trials not otherwise subject to submission requirements under section 402(j) of the PHS Act or this final rule increases public access to information about clinical trials regardless of the apparent nature, quality, or other characteristics of a clinical trial. Making the clinical research enterprise more transparent allows the public to track ongoing trials and informs decision makers involved with clinical trial policies and practices (Section I of this preamble discusses public health benefits of registration and results reporting).

One commenter suggested that the Agency develop results templates for observational studies, which some sponsors may want to report at *ClinicalTrials.gov.* Observational studies that are not pediatric postmarket surveillances of a device are not subject to section 402(j) of the PHS Act. In the future, we may consider developing tools to assist sponsors who provide optional results information for observational studies (other than certain pediatric postmarket surveillances of a device product that are not a clinical trial), which are outside the scope of this rule. The Agency does provide online access to results templates for interventional studies to assist and guide responsible parties in submitting results information under section 402(j) of the PHS Act [Ref. 111].

Another commenter sought clarification about whether linking study results that have been published or posted on another Web site would be permitted for clinical trials that were voluntarily submitted with registration information only. *ClinicalTrials.gov* currently provides a number of optional data elements such as Citations and Links, which can be used to link a record to relevant trial results cited in publications or are available at a another Web site, respectively. These optional data elements will continue to be available on *ClinicalTrials.gov.* Note that, as discussed in greater detail in Section III.B of this preamble, such links to other studies and Web sites from *ClinicalTrials.gov* do not constitute a government affirmation or verification that the information within or referenced in the database, or communications that rely on that information, are truthful and non-misleading.

Final Rule

Taking into consideration the commenters' suggestions and the statutory requirements for voluntary submissions, the final rule retains the requirements as proposed in § 11.60(a), but modifies the statement from proposed § 11.60(b) to accompany voluntarily submitted applicable clinical trials and clarifies that "drug" means "drug product" and "device" means "device product." In addition, consistent with the discussion in Section IV.F of this preamble, we have made revisions to address the differing requirements that apply to applicable clinical trials (and, if voluntarily submitted, other clinical trials).

Section 11.60(a) applies to clinical trials initiated before the effective date of the final rule and that have a primary completion date before the effective date of the final rule. Consistent with the discussion in Section IV.F, below, those clinical trials would be subject to the registration requirements specified in section 402(j)(2)(A)(ii) of the PHS Act and subject to results information submission requirements specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act. Section 11.60(b) applies to clinical trials initiated before the effective date of the final rule and that have a primary completion date on or after the effective date of the final rule. Consistent with the discussion in Section IV.F, below, those clinical trials would be subject to the registration requirements specified in section 402(j)(2)(A)(ii) of the PHS Act and subject to results information submission requirements specified in 42 CFR part 11. Section 11.60(c) applies to clinical trials initiated on or after the effective date of the final rule and that have a primary completion date on or after the effective date of the final rule. Consistent with the discussion in Section IV.F, below, those clinical trials would be subject to the registration and results information submission requirements specified in 42 CFR part 11.

Section 11.60(a)(1), (b)(1), and (c)(1) specify that the requirements for voluntary submission of clinical trial information apply to two types of clinical trials for which submission of information is not otherwise required, as follows: (1) Clinical trials of FDA-regulated drug products (including biological products) or device products that do not meet the definition of an applicable clinical trial (*e.g.,* a phase 1 drug trial or small feasibility device study); and, (2) clinical trials that are applicable clinical trials that were initiated on or before September 27, 2007, and that reached their completion dates before December 26, 2007 (*i.e.,* applicable clinical trials not required to be registered under section 402(j)(2)(C) of the PHS Act or § 11.22(a), as applicable). We interpret section 402(j)(4)(A) of the PHS Act in a way that is consistent with the scope of FDA's regulatory authorities and the scope of this regulation. Thus, § 11.60 applies only to clinical trials of FDA-regulated drug products (including biological products) and device products. For example, this section applies to a phase 1 trial of an FDA-regulated drug product (including a biological product) or a small clinical trial that evaluates the feasibility of an FDA-regulated device product, but does not apply to a clinical trial that studies only behavioral interventions that are not drug products (including biological products) or device products.

In addition, as explained in the proposed rule, we interpret the phrase "applicable clinical trial that is not subject to [the mandatory registration requirement of] paragraph (2)(C)," in section 402(j)(4)(A) of the PHS Act, to mean a clinical trial that meets the definition of an applicable clinical trial, as specified in section 402(j)(1)(A) of the PHS Act and this part, but that was initiated on or before September 27, 2007, and that reached its completion date prior to December 26, 2007 (79 FR 69647).

In considering the information that must be submitted to *ClinicalTrials.gov* for a voluntarily submitted clinical trial, we interpret section 402(j)(4)(A) of the PHS Act as permitting a responsible party to voluntarily submit registration information for a clinical trial, results information, or both. Thus, § 11.60(a)(2)(i), (b)(2)(i), and (c)(2)(i) expressly permit the voluntary submission of registration information, results information, or both. When a responsible party voluntarily submits only registration information for a clinical trial, § 11.60(a)(2)(i)(A), (b)(2)(i)(A), and (c)(2)(i)(A) establish that registration information specified in section 402(j)(2)(A)(ii) of the PHS Act or specified in § 11.28(a) (as applicable) must also be submitted.

For clinical trials with a primary completion date on or after the effective date, § 11.60(b)(2)(i)(B) and (c)(2)(i)(B) specify that when a responsible party voluntarily submits results information for a clinical trial for which registration information is specified in section 402(j)(2)(A)(ii) of the PHS Act or specified in § 11.28(a) (as applicable) has not been submitted, results information as specified in § 11.48(a), as well as additional descriptive information set forth in § 11.60(b)(2)(i)(B) and (c)(2)(i)(B) and defined in § 11.10(b), must be submitted. We believe that such additional descriptive information is necessary to enhance access to and understanding of the results of a clinical trial of a drug product (including a biological product) or device product (*e.g.,* Study Phase is necessary to enable a user to understand the relative stage of development of an experimental drug product (including a biological product) studied in a clinical trial). Further, we believe that several other data elements must be submitted with voluntarily submitted results information in order for the Agency to confirm that a clinical trial for which information is voluntarily submitted is not an applicable clinical trial subject to mandatory registration or results information submission under this part (*e.g.,* Product Manufactured in and Exported from the U.S., and U.S. Food and Drug Administration IND or IDE Number). For situations in which a responsible party submits voluntarily only clinical trial results information under section 402(j)(4)(A) of the PHS Act, the Agency is using its authority under section 402(j)(3)(D)(iii)(IV) of the PHS Act to interpret results information to include the data elements under § 11.60(a)(2)(i)(B) and (c)(2)(i)(B) in addition to the data elements set forth in § 11.48(a). We have added § 11.60(a)(2)(i)(C), (b)(2)(i)(C), and (c)(2)(i)(C) to clarify that a responsible party who voluntarily submits registration information and voluntarily submits results information for a clinical trial must submit registration information as specified in section 402(j)(2)(A)(ii) of the PHS Act or specified in § 11.28(a) (as applicable) and results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act or specified in § 11.48(a) (as applicable).

Sections 11.60(a)(2)(ii), (b)(2)(ii), and (c)(2)(ii) require that a responsible party who submits clinical trial information voluntarily for a clinical trial must additionally submit clinical trial information for any applicable clinical trial (including those initiated on or before September 27, 2007, and reached their completion date prior to December 26, 2007) that is required to be submitted in a marketing application or premarket notification to FDA for approval, licensure, or clearance of the drug product (including a biological product) or device product for the use studied in the voluntarily submitted clinical trial. The final rule maintains the approach in the proposed rule by clarifying that this statutory requirement applies to (1) applications or premarket notifications submitted to the FDA by a manufacturer on or after September 27, 2007; and (2) when the responsible party for the voluntarily submitted clinical trial is also the manufacturer submitting the marketing application or premarket notification, thereby avoiding the situation in which a responsible party would be required to submit information for triggered applicable clinical trials for which they are not the responsible party and do not have access to the relevant data. While the Agency encourages submissions of registration information and results information for all types of clinical trials, regardless of whether they are subject to section 402(j) of the PHS Act, responsible parties should consider the above requirements before deciding whether to register a clinical trial or submit results information voluntarily.

In the final rule, § 11.60(a)(2)(iii), (b)(2)(iii), and (c)(2)(iii) specify that the clinical trial information required to be submitted for a triggered applicable clinical trial is, at minimum, the same as that for the voluntarily submitted clinical trial. That is, if a responsible party voluntarily submits registration information for a clinical trial pursuant to § 11.60(a), the responsible party must submit registration information specified in section 402(j)(2)(A)(ii) of the PHS Act for any triggered applicable clinical trial(s). Similarly, if a responsible party voluntarily submits clinical trial results information for a clinical trial pursuant to § 11.60(a), then the responsible party must submit results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act for any triggered applicable clinical trial(s). Since the submission of clinical trial information for a triggered applicable clinical trial is a condition of voluntary submission, the Agency does not propose to treat the submission of such information as a voluntary submission under § 11.60(a)(2)(ii), (b)(2)(ii), and (c)(2)(ii) that itself could trigger the submission of clinical trial information for other applicable clinical trials. In other words, the submission of information for an applicable clinical trial that is triggered under section 402(j)(4)(A) of the PHS Act and subject to § 11.60 would not, in turn, itself trigger the requirement to submit information for additional applicable clinical trials under that section. For example, voluntary submission of information for trial X may trigger the submission of information for applicable clinical trials Y and Z that were required to be included in FDA marketing application 001, as required under § 11.60(a)(2)(ii), (b)(2)(ii), and (c)(2)(ii). However, submission of information for applicable clinical trials Y and Z would not further trigger the requirement to submit information for additional applicable clinical trials (*e.g.,* even if applicable clinical trial Y were used to support marketing application 002, the applicable clinical trials required to be included in 002 would *not* be triggered).

In general, an initial voluntary submission is not subject to any regulatory deadlines in §§ 11.24 and 11.44 and so may be submitted at any time in relation to the conduct of the trial (*e.g.,* before, during, or after the study start date or primary completion date). However, when a voluntary submission is made, § 11.60(a)(2)(iv), (b)(2)(iv), and (c)(2)(iv) establish two deadlines that apply to voluntary submissions of results information. Sections 11.60(a)(2)(iv)(A), (b)(2)(iv)(A), and (c)(2)(iv)(A) specify that if data collection for the secondary outcome measure(s) or the pre-specified timeframe for collecting adverse event information for such clinical trials is not completed by the primary completion date of the voluntarily submitted clinical trial, then results information for the secondary outcome measure(s) and/or adverse event information must be submitted by the later of either the date that the results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date on which (1) the final subject was examined or received an intervention for the purposes of final collection of data for the secondary outcome measure(s) or (2) after the final subject was observed for adverse events, whether the clinical trial was concluded according to the pre-specified protocol or was terminated. We clarify that while initial voluntary submission of partial results information is permitted (pending completion of data collection for secondary outcomes and/or the pre-specified time frame for collecting adverse events information according to the reporting deadlines specified in § 11.60(a)(2)(iv)(A), (b)(2)(iv)(A), and (c)(2)(iv)(A)), the responsible party is required to submit the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) or specified in § 11.48(a) (as applicable) that is otherwise available when submitting partial results information. This means that, with respect to adverse event information, a responsible party would be required to submit information summarizing serious and frequent adverse events recorded to-date each time results information for a secondary outcome is submitted, until all the adverse event information required by this part has been submitted. This clarification is now included in the final rule in § 11.60(a)(2)(iv)(A)(*2*), (b)(2)(iv)(A)(*2*), and (c)(2)(iv)(A)(*2*). We emphasize, however, this provision does not impose requirements on the design or conduct of the clinical trial or on the data that must be collected during the clinical trial.

Sections 11.60(a)(2)(iv)(B), (b)(2)(iv)(B), and (c)(2)(iv)(B) specify that clinical trial information for triggered applicable clinical trials must be submitted not later than the date on which the application or premarket notification is submitted to FDA or the date on which clinical trial information is submitted for the voluntarily submitted clinical trial to *ClinicalTrials.gov,* whichever is later. This approach prevents a responsible party from having to submit information for a clinical trial that is not subsequently included in the marketing application or premarket notification. Section 11.60(c)(2)(v) specifies that responsible parties who voluntarily submit clinical trial information to *ClinicalTrials.gov* would be required to update and correct submitted information, including information submitted for triggered trials, in accordance with § 11.64 (as applicable).

Section 11.60(d) specifies the text of the statement to accompany voluntarily submitted applicable clinical trials to clarify that the voluntary submission was not subject to the deadlines imposed by section 402(j) of the PHS Act for mandatory submission of registration and results information. The required statement would apply to any applicable clinical trial, including any triggered applicable clinical trial, submitted under section 402(j)(4)(A) of the PHS Act and § 11.60(a), (b), and (c). Accordingly, the statement will be as follows: "This clinical trial information was submitted voluntarily under the applicable law and, therefore, certain submission deadlines may not apply. (That is, clinical trial information for this applicable clinical trial was submitted under section 402(j)(4)(A) of the Public Health Service Act and 42 CFR 11.60 and is not subject to the deadlines established by sections 402(j)(2) and (3) of the Public Health Service Act or 42 CFR 11.24 and 11.44.)"

2. § 11.62—What requirements apply to applicable clinical trials for which submission of clinical trial information has been determined by the Director to be necessary to protect the public health?

Overview of Proposal

The NPRM, in accordance with section 402(j)(4)(B) of the PHS Act, proposed in § 11.62 to require submission of clinical trial information if the Director determines that the posting of such information on *ClinicalTrials.gov* is necessary to protect the public health. Section 402(j)(4)(B)(i) of the PHS Act specifically authorizes the Secretary to "require by notification" of the submission of clinical trial information "in any case in which the Secretary determines for a specific clinical trial [. . . .] that posting in the registry and results data bank of clinical trial information for such clinical trial is necessary to protect the public health." This authority has been delegated to the Director (74 FR 19973, Apr. 30, 2009). If the Director so determines, clinical trial information must be submitted for that clinical trial in accordance with sections 402(j)(2) and (3) of the PHS Act, except with regard to timing requirements. With respect to timing, such clinical trial information must be submitted to *ClinicalTrials.gov* "not later than 30 days after the date specified by the [Director] in the notification," unless the responsible party submits a certification for delayed results information submission under section 402(j)(3)(E)(iii) of the PHS Act (see section 402(j)(4)(B)(i)(II) of the PHS Act).

The NPRM proposed in § 11.62(a) to implement this provision by requiring the responsible party for an applicable clinical trial who receives notification pursuant to section 402(j)(4)(B) of the PHS Act that the Director has determined that posting of clinical trial information is necessary to protect the public health to submit such information to *ClinicalTrials.gov* in accordance with proposed § 11.62(c) (79 FR 69650).

The NPRM proposed in § 11.62(b) to implement section 402(j)(4)(B)(ii) of the PHS Act, which specifies that the types of clinical trials subject to this provision are limited to those that are: (1) "an applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of [the PHS Act] or for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or section 520(m) of [the FD&C Act], whose completion date is on or after the date 10 years before the date of the enactment of the Food and Drug Administration Amendments Act of 2007" (*i.e.,* September 27, 1997) or (2) an applicable clinical trial that is subject to registration under section 402(j)(2)(C) of the PHS Act and studies a drug or device that is unapproved, unlicensed, or uncleared regardless of whether or not approval, licensure, or clearance was sought as described in section 402(j)(3)(D)(ii)(II) of the PHS Act (79 FR 69650).

Section 11.62(c) of the NPRM specified that such clinical trial information must be submitted to *ClinicalTrials.gov* not later than 30 calendar days after the date specified by the Director in the notification, unless the responsible party submits a certification for delayed results submission, as specified in § 11.44(b) or (c). It further proposed that if the responsible party submitted clinical trial registration information prior to the date on which the notification is sent to the responsible party, the responsible party must then make all necessary updates, if any, to the submitted information not later than 30 calendar days after the date specified in the notification (79 FR 69650). The Agency invited public comment on the types of situations in which the posting of clinical trial information might be necessary to protect the public health and on the criteria that the Director should consider when making such a determination, but no comments were received on the types of trials that should be included.

Comments and Response

One commenter addressed proposed § 11.62. The comment suggested that the Agency should describe the criteria to be used by the Director to determine when applicable clinical trials subject to § 11.62 would be required to submit clinical trial information to *ClinicalTrials.gov.* The Agency will issue guidance at a later date on factors that the Director intends to consider in determining whether clinical trial information subject to § 11.62 must be posted on *ClinicalTrials.gov.* We expect this authority to be rarely invoked and limited to extraordinary circumstances including those in the interest of public health or in the interest of national security.

Final Rule

Taking into consideration the commenter's suggestion and the statutory requirements for applicable clinical trials for which submission of clinical trial information has been determined by the Director to be necessary to protect the public health, the final rule maintains the proposed § 11.62 approach, except we clarify that "drug" means "drug product" and "device" means "device product" in final § 11.62(b)(1) and 11.62(b)(2). We also clarify in final § 11.62(b)(2) that the applicable clinical trial is subject to this section "regardless of whether approval, licensure, or clearance was, is, or will be sought, and that is not otherwise subject to results information submission in accordance with the regulation." As explained in the discussion of § 11.10 of this preamble (Section IV.A.5), approval status of a product studied in an applicable clinical trial (*i.e.,* either "unapproved, unlicensed, or uncleared" or "approved, licensed, or cleared") is interpreted to be the approval status of the product on the primary completion date. In this context, the approval status of the product is the approval status on the estimated or actual primary completion date on the date that the Director notifies the responsible party that clinical trial information must be submitted to *ClinicalTrials.gov* for an applicable clinical trial under § 11.62.

The clinical trials specified in § 11.62(b)(1) would consist of applicable clinical trials of approved, licensed, or cleared drugs (including biological products) or devices that reached their primary completion dates on or after September 27, 1997. We note that this set of clinical trials would include applicable clinical trials that reach their primary completion dates on or after the date of enactment of FDAAA, many of which already would be subject to the registration and results information submission requirements of section 402(j) of the PHS Act, with the exception of applicable clinical trials that were initiated prior to the date of enactment of FDAAA (*i.e.,* September 27, 2007) and were not ongoing as of December 26, 2007.

The clinical trials specified in § 11.62(b)(2) would consist of applicable clinical trials that are required to register at *ClinicalTrials.gov* pursuant to § 11.22(a) of this rule and that study drugs (including biological products) or devices that are unapproved, unlicensed, or uncleared by the FDA (regardless of whether or not approval, licensure, or clearance was sought). This set of clinical trials would consist of registered applicable clinical trials that would not otherwise be required to submit clinical trial results information to *ClinicalTrials.gov.*

Section 11.62(c) specifies which information must be submitted to *ClinicalTrials.gov* and the timelines for submitting such information. In general, we interpret the references to "clinical trial information" and submission "in accordance with paragraphs (2) and (3)" in section 402(j)(4)(B)(i)(I) of the PHS act to mean registration information and results information as required in §§ 11.28(a) and 11.48(a), respectively. Consistent with section 402(j)(4)(B)(i)(II) of the PHS Act, such information must generally be submitted not later than 30 calendar days after the date specified by the Director in the notification. We note that section 402(j)(4)(B)(i)(II) of the PHS Act permits an exception to the submission deadline for results information if a responsible party submits a certification for delayed results information submission not later than 30 days after the submission date specified by the Director in the notification. We also note that if the responsible party has submitted such a certification under § 11.44(b) or (c), only the submission of results information will be delayed. Accordingly, if a responsible party for an unregistered applicable clinical trial subject to § 11.62 submits a certification not later than 30 calendar days after the submission date specified in the Director's notification, the responsible party still would be required to submit registration information not later than 30 calendar days after the submission date specified in the notification, although results information would be required to be submitted by the applicable deadline established under § 11.44(b) or (c).

To clarify the submission requirement in situations in which registration information was submitted to *ClinicalTrials.gov* before a notification was sent to the responsible party, § 11.62(c)(3) indicates that the registration information must be updated, if necessary, not later than 30 calendar days after the submission date specified in the notification. Notwithstanding this initial update, the requirements of § 11.64 would apply to clinical trial information submitted pursuant to § 11.62.

All clinical trial information submitted to *ClinicalTrials.gov* under § 11.62 will be subject to the quality control procedures described in § 11.64(b)(1). The Agency intends to post such information as soon as practicable after it has completed the quality control review process. The timeline for posting would apply to all clinical trial information submitted under § 11.62, including registration information for an applicable clinical trial of a device that has not previously been approved or cleared by the FDA. Section 402(j)(4)(B) of the PHS Act applies equally to applicable clinical trials of drugs and devices that are approved, licensed, or cleared or are unapproved, unlicensed, or uncleared. It applies to "any case" in which the Director, as delegated by the Secretary, determines that posting of clinical trial information on *ClinicalTrials.gov* (not just submission of the information to *ClinicalTrials.gov*) is necessary to protect public health. Although section 402(j)(4)(B) of the PHS Act specifically allows for a delay in submission of results information if the responsible party submits a certification for delayed results information submission under section 402(j)(3)(E)(iii) of the PHS Act, it does not specifically delay or prohibit posting submitted registration information until a device is cleared or approved. Therefore, the Agency believes that registration information for all applicable clinical trials under § 11.62 may be posted after quality control review has concluded, regardless of the approval, licensure, or clearance status of the device products studied. Of note, we do not interpret section 402(j)(4)(B) of the PHS Act to permit a responsible party to request a waiver of the requirement to submit clinical trial information pursuant to a notification from the Director under § 11.62. The language of section 402(j)(4)(B) of the PHS Act states "Notwithstanding paragraphs (2) and (3)" (note that waivers are in paragraph (3)), and only makes the exception for trials with a certification for delayed results information submission, as described above. Therefore, it does not make an exception for trials for which a waiver was granted.

3. § 11.64—When must clinical trial information submitted to *ClinicalTrials.gov* be updated or corrected?

Proposed §§ 11.64 and 11.66, which described the requirements and procedures for clinical trial information updates and corrections respectively, are combined in the final rule under the new § 11.64—*When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected?,* described herein.

Overview of Proposal

When must clinical trial information submitted to *ClinicalTrials.gov* be updated?

Section 402(j)(3)(D)(v)(IV) of the PHS Act provides that the regulations shall also establish "the appropriate timing and requirements for updates of clinical trial information, and whether and, if so, how such updates should be tracked." Section 402(j)(4)(C) of the PHS Act separately requires responsible parties to submit updates of clinical trial registration information to *ClinicalTrials.gov* not less than once every 12 months (except for certain specified data elements for which more rapid updates are required) and the Director to post such updates publicly in the data bank. With regard to the requirement in section 402(j)(3)(D)(v)(IV) of the PHS Act to establish, by regulation, "the appropriate timing and requirements for updates of clinical trial information . . .," we noted in the NPRM that we interpret the term "clinical trial information" to mean both clinical trial registration information and clinical trial results information, consistent with the definition of "clinical trial information" in section 402(j)(1)(A)(iv) of the PHS Act. In addition, our proposed requirements for updates apply to adverse event information because adverse event information is deemed to be clinical trial results information under section 402(j)(3)(I)(v) of the PHS Act (79 FR 69587).

Proposed § 11.64(a)(1) established a general requirement for responsible parties to update clinical trial information not less than once every 12 months if there are changes to any of the data elements previously submitted. Section 11.64(a)(2) emphasized that this requirement to update clinical trial information not less than once every 12 months includes a requirement to update the estimated Primary Completion Date data element, unless there have been no changes in the preceding 12 months. We noted that, in our view, the public should be able to rely upon the accuracy of this date to assist them in determining when results information may be available on *ClinicalTrials.gov.* In general, we recommended that the complete clinical trial record on *ClinicalTrials.gov* be reviewed not less than once every 12 months to help ensure that the clinical trial information it contains remains accurate. Proposed § 11.64(a)(3) specified that updates to clinical trial information must be submitted until the date on which all required clinical trial results information has been submitted to *ClinicalTrials.gov,* meaning results for all primary and secondary outcome measures and all adverse events collected in accordance with the protocol. After that time, the proposed rule stated, submitted clinical trial information would continue to be subject to the corrections provisions in proposed § 11.66 of the NPRM, and responsible parties would be required to submit corrected information when the responsible party or the NIH becomes aware of any errors or needed corrections in the clinical trial information (79 FR 69651).

Proposed § 11.64(b) identified data elements that must be updated not later than 30 calendar days after a change occurs, including those already specified in section 402(j)(4)(C)(i) of the PHS Act (*i.e.,* Recruitment Status and Clinical Trial Completion Status). Additional data elements identified for more frequent updates were: Study Start Date; Intervention Name(s); Availability of Expanded Access; Expanded Access Status; Overall Recruitment Status and, if the status changes to suspended, terminated, withdrawn, an explanation about why the study was stopped; and if the status change is terminated or active, not recruiting, the actual enrollment data; Individual Site Status; Human Subjects Protection Review Board Status; Completion Date; Responsible Party, by Official Title; and Responsible Party Contact Information. Furthermore, § 11.64(b) proposed an even more frequent update timeline of not later than 15 calendar days for updating the U.S. FDA Approval, Licensure, or Clearance data element, and stated that the Record Verification Date must be updated any time the responsible party reviews the complete record for accuracy, even if no other updates are submitted at that time (79 FR 69653). It also specified that if a protocol is amended in such a manner that changes are communicated to participants in the clinical trial, updates to relevant clinical trial information must be submitted no later than 30 calendar days after the protocol amendment is approved by the human subjects protection review board (79 FR 69587).

We noted that the above exceptions to the 12-month period for updates are considered important for patients using the data bank to search for clinical trials for which they might qualify and for the Agency in administering other provisions of section 402(j) of the PHS Act. In addition, proposed § 11.64(c) would require a responsible party to update, as necessary, any previously submitted clinical trial information at the time results information is submitted to *ClinicalTrials.gov* (the responsible party would then be required to update the Record Verification Date data element). The NPRM suggested that doing so will improve the accuracy of information that is used by *ClinicalTrials.gov* to automatically prepopulate some elements of results information. As set forth in proposed § 11.64(d)(2), submitted clinical trial information that is posted in accordance with §§ 11.35 and 11.52, including past updates of posted submissions, are tracked in the *ClinicalTrials.gov* archive, in which the history of changes to clinical trial information for any clinical trial is accessible to the public (79 FR 69587).

What are the requirements for corrections of clinical trial information?

Proposed § 11.66 of the NPRM set out requirements for responsible parties to correct clinical trial information submitted to *ClinicalTrials.gov.* This included clinical trial information voluntarily submitted under section 402(j)(4)(A) of the PHS Act and/or proposed § 11.60, as well as clinical trial information necessary to protect the public health and submitted under section 402(j)(4)(B) of the PHS Act and/or proposed § 11.62. Proposed § 11.66 addressed several types of corrections (*i.e.* correction of errors, correction of falsified data and other corrections). The discussion in the NPRM preamble regarding § 11.66 indicated that some errors and other deficiencies are expected to be detected during quality review procedures conducted by the Director (79 FR 69654). Section 402(j)(3)(D)(v)(III) of the PHS Act states that regulations shall establish "procedures for quality control . . . with respect to completeness and content of clinical trial information under this subsection, to help ensure that data elements are not false or misleading and are non-promotional." The discussion of "Quality Control Procedures" in Section III.C.12 of the NPRM outlined the quality control process that would occur with clinical trial information as part of submission. This included a two-step process by which an automated system-based check would occur prior to submission followed by a detailed, manual review after submission. This detailed review would be based on quality review criteria for identifying apparent errors, deficiencies, or inconsistencies that are not detected by the automated checks. If any such problems are identified in the detailed, manual review, the proposed rule stated, the Director would send an electronic notification to the responsible party, indicating that the submission contains apparent errors, deficiencies, and/or inconsistencies listing such issues and requesting correction. Consistent with proposed § 11.66 on correction of errors, the NPRM further outlined that responsible parties would be required to correct the errors, deficiencies, and/or inconsistencies in clinical trial information not later than 15 calendar days after being informed of them by the Agency (or otherwise becoming aware of them), whichever is later. The NPRM also recognized that because clinical trial information will have to be posted not later than the 30 day posting deadlines specified in §§ 11.35 and 11.52, there may be some situations in which submitted clinical trial information is posted before it has been corrected. We noted that it would be necessary to include information indicating that such information has not completed the quality control process as well as implementing other mechanisms to help users of *ClinicalTrials.gov* identify such clinical trial records (79 FR 69586).

Although the statute did not establish timelines for correcting errors, § 11.66 proposed that corrections needed to be submitted after the responsible party becomes aware that submitted clinical trial information is incorrect or falsified or that corrections are needed for other reasons. Section 11.66(a) required responsible parties to correct errors not later than 15 calendar days after the error is discovered. Section 11.66(b) covered falsified data and proposed to require notification to the Director of the falsification and submission of corrected information not later than 15 calendar days after the corrected information becomes available or notification not later than 15 calendar days after determining that the information cannot be corrected or is correct. Section 11.66(c) addressed "other corrections of clinical trial information" which were identified as "various other deficiencies" including but not limited to "inconsistencies in submitted data, for example, a mismatch between the reported number of subjects enrolled in a clinical trial and the sum of reported number of subjects assigned to different arms . . ."(79 FR 69655) and stated that a responsible party who becomes aware or is informed by NIH that such corrections are needed must make them as soon as possible but not later than 15 calendar days after becoming aware or being informed of the problem.

Comments and Response

When must clinical trial information submitted to *ClinicalTrials.gov* be updated?

Commenters addressed the update provisions in § 11.64, with some in support of the proposed approach, while others suggested changes to the required updates and the proposed timelines. Among those who suggested changes, commenters suggested that the specific timelines for updates were too short. Some commenters suggested alternative timelines for updates, including that the general timeline for updates should be extended from not less than once every 12 months to once every 18 months; the 30-day timeframe for rapid updates should be extended to 45 or 60 days; and that all the timelines for each rapid update element should be consistent (*i.e.*, the timeline for updating the U.S. FDA Approval, Licensure, or Clearance data element should also be 30 calendar days). Although commenters suggested extending the timelines, the 12 month general timeline is established by section 402(j)(4)(C)(i)(I) of the PHS Act. Similarly, the 30 day timeline following changes to Overall Recruitment Status and Completion Date is established by section 402(j)(4)(C)(i)(III) and section 402(j)(4)(C)(i)(IV) of the PHS Act. While the statute would allow for modifying the 30 day timeline for other data elements, sufficient evidence of burden was not provided by the public comments indicating that these deadlines would be difficult to meet. Moreover, we believe it makes sense, in the interest of simplicity (as has also been sought by commenters), to keep the timeline for updates consistent to the extent possible. Finally, rapid updating of this information is consistent with the stated purpose of *ClinicalTrials.gov* set forth in section 402(j)(2)(A)(i) of the PHS Act to "enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials." If such key changes were not reflected in the record in *ClinicalTrials.gov* for as long as 12 months after the change, then the Agency believes that the value of *ClinicalTrials.gov* as a source of reliable, accurate information for the public and potential participants in clinical trials would be compromised.

Commenters also raised issues regarding specific data element update requirements. One disagreed with the requirement that actual enrollment data be provided when the Overall Recruitment Status changes (*i.e.*, trial's recruitment status changes to "terminated" or "active, not recruiting") and suggested that the NIH continue to allow submission of actual enrollment data at the time of overall study completion (*e.g.*, LPLV). The Agency believes that submission of actual enrollment information at the time that recruitment is no longer occurring (Overall Recruitment Status is "terminated" or "active, not recruiting") would permit users of *ClinicalTrials.gov* to know more quickly whether the clinical trial achieved its target enrollment. However, we also recognize the potential burden and some of the challenges with providing such information in a more rapid manner. In the final rule, therefore, we modify the requirement to be consistent with current practice at *ClinicalTrials.gov* by requiring actual enrollment to instead be updated within 30 calendar days of reaching the Primary Completion Date.

Another commenter opposed the requirement that the status of individual sites be updated because of concerns about burden on large international trials. The Agency believes that changes in recruitment status should be communicated promptly so that potential human subjects can know whether or not a clinical trial is currently recruiting subjects. In addition, prompt updates to Overall Recruitment Status as well as Individual Site Status support the purpose of *ClinicalTrials.gov* to enhance patient enrollment by assisting potential human subjects who search for clinical trials by location and wish to retrieve information about only those trials that are open to recruitment in specified locations. We clarify that when the Overall Recruitment Status is other than "recruiting," the Individual Site Status no longer needs to be updated because a change in the Overall Recruitment Status would apply to each individual site and the Individual Site Status will no longer be displayed by *ClinicalTrials.gov* on the publicly posted study record. We also note that the update burden to responsible parties is reduced by tools available in the PRS that allow for easily changing the Individual Site Status (*e.g.*, from "recruiting" to "active, not recruiting") for many sites at once.

Another commenter raised a question about which IRB approval date is relevant in a multi-site trial involving multiple IRBs in response to the requirement to update the record not later than 30 calendar days after an amended protocol is approved by an IRB that involves changes that are communicated to participants. We clarify that the date of the first IRB approval for the amendment should be used. We note that we invited public comment on other thresholds (other than those changes that are communicated to enrolled participants) that could be used to determine which protocol changes are significant enough to warrant 30-day updating of affected clinical trial information, but none was received.

Comments were also raised in opposition to the proposal to require voluntarily registered trials to comply with the update and correction timelines due to the burden involved. It was suggested that the requirement may have the unintended consequence of decreasing voluntary submissions and, thereby, transparency. The Agency believes that in order to maintain the value of *ClinicalTrials.gov* as a source of accurate and up-to-date clinical trial information each record, including voluntary submissions, must be updated in accordance with the timelines outlined in the final rule. Other commenters requested that a mechanism be included in the PRS to make clear to responsible parties when they have fulfilled all obligations to update the study record, and no further updates are required. Proposed § 11.64(a)(3) indicated that the responsible party must continue to submit updates until complete "clinical trial results information specified in § 11.48 has been submitted for all primary and secondary outcomes and all adverse events that were collected in accordance with the protocol." We agree with the commenters on the need for being able to identify when the obligation to update and/or correct clinical trial information has ended. As one component of this determination, we have added to §§ 11.10(a) and 11.28, the Study Completion Date data element to identify "the date the final subject was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (*e.g.*, last subject's last visit) . . ." Providing the Study Completion Date as clinical trial information and including it as a data element that must be updated within 30 calendar days of a change is consistent with the stated purpose of *ClinicalTrials.gov* to ". . . provide a mechanism to track subsequent progress of clinical trials" (see section 402(j)(2)(A) of the PHS Act). Further, it establishes the date on which the final subject was examined (or received an intervention) for purposes of final data collection, thereby identifying the maximum date under § 11.44(d) by which partial results information must be submitted (*i.e.*, no later than one year after the Study Completion Date).

The NPRM indicated that the obligation to update ends after submission of complete clinical trial results information. We clarify that the obligation to submit updates ends after all required clinical trial results information has been submitted as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act or as specified in § 11.48, as applicable, and after any corrections have been made or addressed as required under § 11.64(b). We note that one reason it is important for the update requirements to continue through the conclusion of the quality control process is to ensure that the Responsible Party and Responsible Party Contact Information remains accurate during that process. We also have clarified that for any clinical trials that are not subject to the clinical trial results information submission requirements, the obligation to update ends on the date on which all required clinical trial registration information has been submitted as specified in section 402(j)(2)(A)(ii) of the PHS Act or § 11.28, as applicable, and corrections have been made or addressed in response to any electronic notice received under § 11.64(b)(1).

What are the requirements for corrections of clinical trial information?

Commenters addressing the proposed quality control procedures and/or the corrections provisions proposed in § 11.66 commented on the amount of time a responsible party has to correct clinical trial information, timing of posting of clinical trial information in relationship to quality control procedures, and the falsified data provisions. Each of these topics is discussed in turn.

Commenters submitting input on the corrections provisions in § 11.66 of the NPRM expressed general support for the requirement to correct errors and some commenters also supported the 15 day timeline for addressing corrections. Other commenters expressed concern about the timeline for correction of errors, as they found it too short and suggested that it was insufficient, unrealistic, and burdensome. Commenters suggested that a rush by responsible parties to meet the deadline might result in the unanticipated submission of more errors. Alternative timeframes were proposed by commenters, who suggested extending the correction of error timeline to 30 days, 45 days, and 60 days. One commenter proposed allowing 15 days for the responsible party to notify the NIH from the time an error is discovered followed by a 30 day timeline to make any corrections. As noted in the NPRM discussion of quality control procedures (Section III.C.12), the Agency expects to conduct a quality control review and also aims to receive submission of corrected clinical trial information prior to the deadlines for posting such information publicly as specified in §§ 11.35 and 11.52 (*i.e.*, not later than 30 calendar days after submission). We are, therefore, maintaining the proposed timeline of 15 calendar days for the responsible party to correct clinical trial registration information after a notification is sent by the Director, but we are extending the timeline for correction of clinical trial results information to "25 calendar days." These timelines are in place for two reasons: (1) To allow, in some cases, corrected clinical trial information to be submitted by the responsible party in a timeline that would allow for quality control review and posting in accordance with the timelines in §§ 11.35 or 11.52; and, (2) to minimize the amount of time that posted clinical trial information is available without conclusion of the quality control review process. In our experience in operating the registry component of *ClinicalTrials.gov*, we have found that clinical trial registration information can be reviewed quickly and that responsible parties can submit corrected information, if necessary, in a matter of days. However, allowing for a longer timeline for corrections of clinical trial results information acknowledges the inherent difference in complexity of the information as compared to clinical trial registration. To better distinguish between corrections that may be needed based on quality control by the Director and other corrections that are needed based on identification by the responsible party, we are modifying the corrections provisions in the final rule to address these separately. When a responsible party becomes aware of errors, the timelines to correct or address such errors are 15 calendar days for registration information and 25 calendar days for results information. We clarify in the discussion of the final rule requirements for corrections, the steps that can be taken when the Director notifies a responsible party of issues.

As initially discussed in the context of §§ 11.35 and 11.52, a number of commenters expressed the importance of quality control and suggested that both registration and results information should be posted only when quality control review criteria have been fulfilled. Commenters expressed concern about the potential to misinform those using the publicly posted study record and suggested only posting sections that have fulfilled quality control criteria. Some commenters suggested that the harm of posting information that has not passed quality control review is greater than posting the information in a timely manner. While we understand these concerns, section 402(j)(3)(G) of the PHS Act established for applicable clinical trials that the Director of NIH is required to post results information "publicly in the registry and results database not later than 30 days after such submission." In addition, because there may be cases in which clinical trial information is posted without conclusion of the quality control review process, a shorter timeline for corrections will minimize the amount of time such records are posted. In the event that a study record is posted in accordance with the statutory posting deadline, and the quality control review has not concluded, the clinical trial record will contain information that will be visible to the public explaining that the quality control review process for the posted clinical trial information has not concluded.

Regarding the proposed statements on a study record, commenters were concerned that users of *ClinicalTrials.gov* may not understand such notices and may make decisions based on information that is inaccurate, unclear, or incomplete. To address this concern, we will evaluate whether there are ways in which the notices for each record could specify the data element(s) identified by the Agency that may contain errors, deficiencies, and/or inconsistencies, and aim to employ other measures to ensure that the notice is clear and limited to the relevant sections. We note that the quality control review process will continue even after the information is posted with a notice indicating the process has not concluded. The general quality control review process and the specific criteria utilized by the Director to evaluate submitted results will be available at *https://prsinfo.clinicaltrials.gov* (or successor site), prior to the effective date, for responsible parties and the public to have a better understanding of the types of issues reviewed.

Responsible parties must correct or address apparent errors, deficiencies, and/or inconsistencies within 15 calendar days (clinical trial registration information) or 25 calendar days (clinical trial results information) of the date the Director provides electronic notification to the responsible party. Quality control review procedures will be followed for any subsequent submission of revised clinical trial information. When the responsible party submits revised clinical trial information, or provides explanatory information that addresses the apparent errors, deficiencies, and/or inconsistencies, any revised information will be posted after quality control review. Further, when all apparent errors, deficiencies, and/or inconsistencies have been addressed, the statement that the quality control review process had not concluded will be removed from the posted record. However, the clinical trial information that was initially posted will appear in the archived history for that clinical trial record, and the archived version will indicate that it had been posted with a notice. The electronic notification sent to the responsible party indicating that the quality control review process has concluded will inform responsible parties of these facts. We hope this notification further encourages those with posted records that contain such a statement to correct the information or address the issues raised by the quality control review process as soon as possible, to help ensure that users of *ClinicalTrials.gov* may rely on the information in the trial records, as intended.

Some commenters requested more information, such as additional guidance regarding quality control processes, while others made suggestions, such as NIH development of common standards for quality control or development of a process that involves domain experts. To assist responsible parties in avoiding such errors, deficiencies, and inconsistencies prior to this final rule, we developed and continued to refine documentation explaining how to meet the quality review criteria; identified and compiled lists of frequent errors, deficiencies, and inconsistencies in submitted results information; and, provided system support to help responsible parties minimize such errors, deficiencies, and inconsistencies. We also have provided intensive user support for responsible parties who are new to the online submission process, particularly for results information, whether through data entry using Web-based forms or automated uploading of data files. In particular, we provide one-on-one assistance to support a responsible party in submitting their clinical trial results information. We have developed and posted draft educational materials, such as tips on improving results information submissions and ways to avoid common errors, deficiencies, and inconsistencies observed in submissions to date. All such documents are available at *https://prsinfo.clinicaltrials.gov* (or successor site). We will continue to provide such support to responsible parties and, based on these interactions, develop new or updated materials in order to facilitate and streamline preparation of clinical trial information for submission to *ClinicalTrials.gov* and to help ensure that the submissions meet the quality review criteria.

Commenters also addressed the falsified data correction provision proposed in § 11.66(b) and suggested that it was vague and unclear about when errors should be reported as falsified data and how responsible parties are to determine when sufficient credible evidence exists to warrant a falsification report. They noted that no guidelines were provided for what events should trigger a presumption that data may be false and what constitutes a suitable investigation, and no distinctions were made about materiality, *e.g.,* inaccuracies about the recruitment status versus inaccuracies about the validity of safety data. Commenters inquired about the sanctions that would go with each determination (error versus falsification) and asserted that a more clearly defined and formal process would need to be in place to ensure a thorough investigation is conducted before inaccuracies are reported as falsified data. In addition, commenters suggested that the falsification provision could result in depriving responsible parties of their right to due process under the Fifth Amendment because it would require companies to report falsification without establishing clear parameters for what constitutes falsification. One commenter asserted that, given that there are criminal penalties for making false statements to the Government, the offense must be sufficiently explicit to inform those who are bound by the law of the specific conduct that will subject them to criminal penalties. A commenter suggested that it was inappropriate to incorporate into the NPRM a definition of falsification from FDA's proposed Reporting Information Regarding Falsification of Data regulation (Docket No. FDA–2008–N–0115, 75 FR 7412 (Feb. 19, 2010)). Commenters also suggested that the certification and falsification provisions should undergo a separate rulemaking process to determine what constitutes falsification and intent, and such process should be used and carried out in conjunction with FDA and other federal biomedical research stakeholders to propose a system for addressing the important and complicated issues related to intentional research falsification. Another commenter suggested that a disclaimer should be included in clinical trial records to inform the public that *ClinicalTrials.gov* is not responsible for the accuracy of the study results. Based on consideration of these comments, the final rule eliminates the distinctions between the types of errors (*i.e.* errors, falsifications, other errors) and simplifies the regulatory approach for correction of errors as described below and in § 11.64(b). From a database integrity standpoint, the distinction between an inadvertent and a deliberate error is not material, and eliminating this distinction is responsive to concerns raised by public comments. However, we emphasize existing mechanisms that address scientific misconduct (see § 11.6 and Section IV.A.3 of this preamble).

Final Rule

Taking into consideration commenters' suggestions regarding both updates (proposed § 11.64) and corrections (proposed § 11.66), as well as the statutory requirements, the final rule combines these sections into the new § 11.64—*When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected?* While both the updates and corrections provisions in these sections include specific timelines by which clinical trial information must be updated or corrected, we encourage responsible parties to update or correct information as soon as possible to help the ensure that posted clinical trial information is accurate and up-to-date for those that rely on the information on *ClinicalTrials.gov.* Additionally, final § 11.64(a) clarifies that "drug" means "drug product."

Required updates are described in § 11.64(a), which generally retains the NPRM proposal for required updates but modifies the requirement for the timing of updating actual enrollment information. Consistent with the revisions discussed in preceding sections of this preamble, § 11.64(a) also adds a requirement to update Study Completion Date and clarifies the requirements for data elements related to expanded access. In addition, we clarify how a responsible party indicates that there were no changes to clinical trial information in the previous 12 month period. Modifications were also made to clarify when a responsible party's obligation to update and correct clinical trial information ends. In addition, consistent with the discussion in section IV.F of this preamble, we made revisions to address the differing requirements that apply to applicable clinical trials (and, if voluntarily submitted, other clinical trials).

For clinical trials initiated before the effective date of the final rule, § 11.64(a)(1)(i)(A) establishes a general requirement for responsible parties to update clinical trial registration information specified in section 402(j)(2)(A)(ii) not less than once every 12 months if there are changes to any of the data elements previously submitted. Section 11.64(a)(1)(i)(B) and (a)(1)(i)(C) detail the requirement to update the Overall Recruitment Status data element not later than 30 calendar days after any change in overall recruitment status and the Primary Completion Date data element not later than 30 calendar days after the clinical trial reaches its actual primary completion date.

For clinical trials initiated on or after the effective date of the final rule, § 11.64(a)(1)(ii)(A) establishes a general requirement for responsible parties to update clinical trial registration information specified in § 11.28 not less than once every 12 months if there are changes to any of the data elements previously submitted. Section 11.64(a)(1)(ii)(B) through (a)(1)(ii)(O) establish requirements for a responsible party to update certain clinical trial registration information more rapidly after a change in the status or conduct of a clinical trial or pediatric postmarket surveillance of a device product. The NIH recognizes that it would be impractical and potentially burdensome to responsible parties to require rapid updates to all clinical trial information data elements each time a change occurs, but we believe that changes to certain data elements beyond those required to be rapidly updated in section 402(j) of the PHS Act are sufficiently time-sensitive to require updates more rapidly than once every 12 months.

Section 11.64(a)(1)(ii) outlines the requirements for updating the following 14 data elements:

(1) *Study Start Date.* The Study Start Date data element must be updated from estimated to actual not later than 30 calendar days after the first human subject is enrolled in the clinical trial. This requirement applies to clinical trials for which an estimated study start date is provided at the time of registration, rather than an actual study start date, *i.e.,* clinical trial registration information was submitted prior to enrollment of the first human subject. The update ensures that potential human subjects know in a timely fashion that recruitment has begun. It also ensures that the record reflects the actual start date, as opposed to an estimated start date, and it provides a mechanism to demonstrate whether a clinical trial has been registered not later than 21 calendar days after enrollment of the first subject.

(2) *Intervention Name(s).* The Intervention Name(s) data element must be updated to a non-proprietary name not later than 30 calendar days after a non-proprietary name is established for an intervention studied in a clinical trial. Intervention Name is frequently used as a search term to identify and retrieve clinical trials of interest. If it is not updated for as long as a year, users of *ClinicalTrials.gov* will not be able to accurately retrieve trials of interest during that time or to easily compare information among multiple trials of the same intervention.

(3) *Availability of Expanded Access.* Clinical trial information submitted under the Availability of Expanded Access data element in § 11.28(a)(2)(ii)(H) must be updated by the responsible party who is both the manufacturer of the drug and the sponsor of the applicable clinical trial not later than 30 calendar days after expanded access becomes available. Similarly, the data element must be updated not later than 30 calendar days after the date on which the responsible party receives an NCT number for the expanded access record. This data element informs patients whether access to an investigational drug product (including a biological product) to treat serious or life-threatening diseases or conditions is available outside of the applicable clinical trial. Expanded access may not be available at the time clinical trial registration information is submitted, and expanded access may no longer be available on a date other than the primary completion date of the applicable clinical trial. Therefore, there are specific update requirements:

First, when expanded access for a particular investigational drug product (including a biological product) becomes available after registration information has been submitted for applicable clinical trial(s) of that investigational product, if the responsible party for the applicable clinical trial(s) is both the manufacturer of the investigational product and the sponsor of the applicable clinical trial, the responsible party must update the Availability of Expanded Access data element in § 11.28(a)(2)(ii)(H) not later than 30 calendar days after expanded access becomes available.

Second, not later than 30 calendar days after expanded access becomes available, if the responsible party is both the manufacturer of the investigational drug product and the sponsor of the applicable clinical trial, the responsible party must create an expanded access record by submitting the data elements required under § 11.28(c), unless an expanded access record for the investigational drug product has already been created. The responsible party is required to enter the NCT number of the expanded access record in the relevant clinical trial record(s) not later than 30 calendar days after the date on which the responsible party receives such NCT number. We note that we have removed the NPRM proposal to also require a responsible party to update the Availability of Expanded Access data element not later than 30 calendar days after termination of the expanded access program. The provision of the NCT number of the expanded access record as well as the requirement to update the Expanded Access Record data element as described in § 11.64(a)(1)(ii)(E) will allow for *ClinicalTrials.gov* to ensure that information on the availability of expanded access is accurately displayed on the relevant posted record(s), while reducing the update burden on a responsible party.

We note that, as discussed below, § 11.64(a)(3) establishes when a responsible party's obligation to submit updates for clinical trial information ends. Even if an investigational product has not been approved or licensed at the time the updating requirement ends, we strongly encourage responsible parties to continue to update the Expanded Access Record until the product is approved or licensed or expanded access is no longer available. Updating this information will provide patients with accurate and up-to-date information about the availability of investigational products, which we believe will facilitate access to such products. Second, updating expanded access records may reduce the burdens on responsible parties who are both the manufacturer and the sponsor of the applicable clinical trial, because patients who are interested in expanded access will be able to rely on the information in *ClinicalTrials.gov*, rather than having to contact the responsible party in order to obtain this information.

(4) *Expanded Access Record.* The Expanded Access Status data element in § 11.28(c)(2)(iv) must be updated not later than 30 calendar days after a change in the status of the availability of expanded access, to indicate whether access to the investigational drug product is currently available. This data element plays a role in providing information about expanded access that is similar to the role of Overall Recruitment Status in applicable clinical trials, indicating whether expanded access is currently available to patients. Expanded Access Type in § 11.28(c)(1)(x) must be updated not later than 30 calendar days after a change in the type of expanded access that is available to patients. The timely update of these data elements is important to have reflected in the data bank and is consistent with statutory requirements.

(5) *Overall Recruitment Status.* This data element must be updated not later than 30 calendar days after a change in the overall recruitment status of the clinical trial. Changes in recruitment status should be communicated promptly so that potential human subjects can know whether or not a clinical trial is currently recruiting subjects. In addition, if Overall Recruitment Status is updated to "suspended," "terminated," or "withdrawn," the responsible party must at the same time provide information for the Why Study Stopped data element. Suspension, termination, and withdrawal of a clinical trial are significant changes that should be communicated promptly to prospective human subjects, along with the reason for the change. The responsible party will be allowed to enter this information as free-text so that he or she has flexibility to explain the reason(s) why a clinical trial stopped prematurely.

(6) *Individual Site Status.* This data element must be updated not later than 30 calendar days after a change in status for any individual site. It also supports the purpose of *ClinicalTrials.gov* to enhance patient enrollment by assisting potential human subjects who search for clinical trials by location and wish to retrieve information about only those trials that are open to recruitment in specified locations.

(7) *Human Subjects Protection Review Board Status.* This data element must be updated not later than 30 calendar days after a change in Human Subjects Protection Review Board Status. Because such information is intended to demonstrate to potential human subjects whether a registered applicable clinical trial or other clinical trial has undergone necessary human subjects protection review board review, has received necessary approvals for human subjects research, or was exempt from such review, it must be updated in a timely fashion.

(8) *Primary Completion Date.* This data element must be updated not later than 30 calendar days after a clinical trial reaches its actual primary completion date. In addition, at the time the date is changed to "actual," the responsible party must also update the Enrollment data element to actual and specify the actual number of participants enrolled.

(9) *Study Completion Date.* This data element must be updated not later than 30 calendar days after a clinical trial reaches its actual study completion date.

(10) *Responsible Party, by Official Title.* This data element must be updated not later than 30 calendar days after a change in either the name of the responsible party or in the responsible party's official title. This update is necessary to enable NIH and other users of the data bank to accurately identify the responsible party for the clinical trial.

(11) *Responsible Party Contact Information.* Consistent with updates required to the Responsible Party data element, the Responsible Party Contact Information must be updated not later than 30 calendar days after a change in the responsible party or the responsible party's contact information. Given that the responsible party must make updates to clinical trial information and, in general, must submit clinical trial results information, it is essential for the Agency to know of changes to the responsible party and to responsible party contact information in a timely manner. Up-to-date information about the responsible party ensures that the Agency has contact information for the appropriate person responsible for submitting clinical trial information about the applicable clinical trial or clinical trial.

(12) *Device Product Not Approved or Cleared by U.S. FDA.* This data element must be updated not later than 15 calendar days after a change in the approval or clearance status of one or more device products studied in the applicable clinical trial. A change in the approval or clearance status of a device product can trigger a requirement for the Agency to post previously-submitted clinical trial registration information within 30 calendar days of the change in status as further discussed in Section IV.B.5 of this preamble. The 15 day deadline is a procedural necessity to provide the Agency timely notice that it must post publicly clinical trial registration information within 30 calendar days of the change in status, as required by law.

(13) *Record Verification Date.* This data element must be updated any time the responsible party reviews the complete set of submitted clinical trial information for accuracy, even if no other updated information is submitted at that time. The record verification date is intended to demonstrate when the information in *ClinicalTrials.gov* for a particular clinical trial was last checked for accuracy. As noted in § 11.28, the responsible party will be required to update the Record Verification Date if he or she examines the complete set of submitted clinical trial information (*e.g.*, as part of a monthly or annual review), even if he or she determines that no additional or updated information needs to be submitted. Similarly, the responsible party will be required to update the Record Verification Date data element if he or she updates a data element and reviews the rest of the record for accuracy. However, the responsible party is not required to update the Record Verification date if he or she submits updates to one or more data elements without reviewing the accuracy of the rest of the record. We clarify that the Record Verification Date must be updated not less than once every 12 months, even if no other updated information is submitted at that time. This approach does not require a responsible party to review records more frequently or regularly than will be needed in order to update submitted information as otherwise required by § 11.64(a), but it does require that the Record Verification Date be updated if the complete record were reviewed for accuracy during such an update and not less than once every 12 months. Doing so indicates to users of *ClinicalTrials.gov* the currency of the information and provides an additional assurance that it is up-to-date.

(14) Subsection 11.64(a)(1)(ii)(O) details that relevant clinical trial

registration information be updated not later than 30 calendar days after a protocol amendment is approved by a human subjects protection review board, if the protocol is amended in such a manner that changes are communicated to participants in the applicable clinical trial or other clinical trial.

In addition, § 11.64(a)(1)(iii) requires that responsible parties update clinical trial registration information at the time they submit clinical trial results information to *ClinicalTrials.gov* (unless there are no changes to the clinical trial registration information). If the clinical trial was initiated before the effective date of the final rule, updates to clinical trial registration information must be submitted as described in § 11.64(a)(1)(i). If the clinical trial was initiated on or after the effective date of the final rule, updates must be submitted in accordance with § 11.64(a)(1)(ii). As discussed further in Section IV.F, this approach is consistent with the Agency's interpretation of the differing requirements that apply to applicable clinical trials initiated before the effective date of the final rule and those initiated on or after the effective date of the final rule. This requirement is intended to help ensure the consistency and accuracy of information in the registry and results portions of the data bank. Updated registration information will be used to pre-populate certain data elements in the clinical trial record so that responsible parties do not have to enter them again. Because the submission and subsequent posting of clinical trial results information is often a reason for users to retrieve the record for a particular clinical trial, the additional update requirement will also ensure that users have access to complete registration and results information that is up-to-date.

For clinical trials that have a primary completion date on or after the effective date of the final rule, § 11.64(a)(2)(i) establishes a general requirement for responsible parties to update clinical trial results information not less than once every 12 months if there are changes to any of the data elements previously submitted. The final rule also clarifies that the protocol and statistical analysis plan specified in § 11.48(a)(5) and certain agreements specified in § 11.48(a)(6)(ii) are excluded from this general requirement as any changes to this content will be submitted as partial results information in § 11.44(d)(3). Section 11.64(a)(2)(ii) requires for applicable device clinical trials of unapproved or uncleared device products that the following data elements, as the data elements are defined in § 11.10(b), be updated not later than 30 calendar days after the relevant changes have occurred: Intervention Name(s), Primary Completion Date, Study Completion Date, and Overall Recruitment Status. The Record Verification Date must be updated any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months. As described in Section IV.C.4 of this preamble for § 11.48(a)(7), we interpret the statute to provide the Secretary the authority to require, through rulemaking, for applicable device clinical trials of unapproved or uncleared device products this additional descriptive information that is similar to the type of information required to be submitted under section 402(j)(2)(A)(ii) of the PHS Act.

Section 11.64(a)(3) specifies that updates to clinical trial information must be submitted until the date on which all required clinical trial results information has been submitted as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act or § 11.48 (as applicable), and all corrections have been made or addressed in response to any electronic notice received under § 11.64(b)(1). Until that point in time, submitted clinical trial information will continue to be subject to the corrections provisions in § 11.64(b), and responsible parties will be required to submit corrected information when the responsible party becomes aware of any errors in the clinical trial information. We have clarified that if no clinical trial results information is required to be submitted, a responsible party's obligation to submit updates ends on the date on which all required clinical trial registration information has been submitted as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act or § 11.28, as applicable, and corrections have been made in response to any electronic notice received under § 11.64(b)(1).

We note that the updating requirements under § 11.64(a) are prompted by changes in the clinical trial and not by changes in the format in which data must be submitted to *ClinicalTrials.gov*. For example, if the Agency were to make administrative changes to the format in which clinical trial information is submitted to *ClinicalTrials.gov* after the responsible party had submitted clinical trial information as required, the Agency's revisions to *ClinicalTrials.gov* would not themselves give rise to a requirement that the responsible party update the previously submitted applicable clinical trial information. For example, if the Agency added additional options to a drop-down menu for a particular data element, even if one of the additional options is more appropriate with respect to an applicable clinical trial, the responsible party would not be required to update its previously-submitted clinical trial information, although the responsible party it could choose to do so on an optional basis. However, if a responsible party makes a required update to previously submitted clinical trial information, for example, to reflect a change in the conduct or progress of a clinical trial, the responsible party is required to submit the updated information in the format required by *ClinicalTrials.gov* at the time the update is submitted. For example, if the set of options in a drop-down menu had changed since the information had previously been submitted, the responsible party is required to select from the new set of options. We also note that if such options were modified, we would provide prior notice and seek public comment as described in Section IV.A.4, as needed.

Updates to clinical trial registration information and clinical trial results information will be posted in accordance with §§ 11.35 and 11.52, respectively. Previously posted clinical trial information will remain publicly available through the *ClinicalTrials.gov* archive. The availability of updates is codified in § 11.64(a)(4).

With regard to the requirements for corrections of clinical trial information, the final rule eliminates the distinction between the three types of corrections described in the NPRM: Errors, falsified data, and other corrections. We clarify, however, that the elimination of "falsification" as a type of error does not reflect a lack of concern about data integrity or tolerance by the Agency for falsification of information, and we emphasize the existing mechanisms that address scientific misconduct and falsifying information submitted to the Government in § 11.6. Instead, § 11.64(b) of the final rule requires a responsible party to correct or address (1) apparent errors, deficiencies, and/or inconsistencies identified by the Director during quality control review of submitted clinical trial information; and, (2) errors in previously submitted information identified by the responsible party. We also reiterate the procedures for quality control review that were originally described in the NPRM in Section III.C.12 and that are directly related to the corrections provisions of this final rule. Overall, we consider corrections of information to be different from updates to information, as described in § 11.64(a). While updates are modifications to clinical trial information that reflect changes in the status or conduct of a clinical trial or the associated analysis, corrections are used to revise submitted clinical trial information that contains errors or appears to be invalid, incorrect, inconsistent, or incomplete. Because problems in clinical trial information that is (or will soon be) posted publicly need to be addressed in a timely manner in order to ensure that accurate information is available to the public, the final rule requires responsible parties to correct or address all such problems not later than 15 calendar days for clinical trial registration information and 25 calendar days for clinical trial results information after electronic notification is sent by the Director or are otherwise identified by the responsible party. A responsible party must then either correct and resubmit the clinical trial information to *ClinicalTrials.gov* or address each identified issue, such as replying by electronic notification to the Director explaining why the information is correct as submitted or why such information cannot be corrected.

Section 11.64(b)(1) specifies the requirements for correcting apparent errors, deficiencies, and/or inconsistencies identified based on quality control review procedures established by the Director (materials explaining how to meet the quality review criteria are available at *https://prsinfo.clinicaltrials.gov* or successor site). Our quality control review process is intended to help ensure that clinical trial information posted on *ClinicalTrials.gov* has facial validity and is free from obvious errors. Examples of errors, deficiencies, and/or inconsistencies that may be identified during the quality control review process include, but are not limited to, inadvertent, typographical errors, such as transpositions of numbers or characters; inadvertent omissions of data, such as omission of one component of set of participant exclusion criteria; inconsistencies in submitted data, for example, a mismatch between the reported number of subjects enrolled in a clinical trial and the sum of reported number of subjects assigned to different arms; and, incomplete entries that are insufficient to convey their intended meaning, such as a description of an outcome measure that does not describe the measurement scale being used. They also include submitted values that are demonstrably wrong, such as a mean age of participants of 624 years.

At the time of submission of clinical trial registration information, clinical trial results information, and any related updates or changes, the Agency will conduct quality control review procedures that are similar to the procedures in place before the final rule and will not affect the statutory deadlines for the submission and updating of clinical trial information (as specified in §§ 11.24, 11.44, and 11.64(a)) or publicly posting submitted clinical trial information (as specified in §§ 11.35 and 11.52). In general, we aim to complete the quality control review process and to receive submissions of corrected clinical trial information prior to the statutory deadlines for posting submitted clinical trial information publicly. We recognize that in some situations, the quality control review process may not be concluded prior to the statutory posting deadlines, and the Agency will post submitted information that may need to be corrected. Clinical trial information posted without having concluded the quality control review process, including any necessary corrections by the responsible party, will include a statement indicating that the quality control review process has not concluded. In addition, as also mentioned in Section IV.B.5 of this preamble, if the quality control review process has not concluded but the clinical trial registration information is posted to the *ClinicalTrials.gov* Web site based on the statutory posting deadline, an NCT number will not be assigned until the quality control review process has concluded. We believe additional precautions must be taken with such clinical trial registration information because it is used by the public, including by patients and healthcare providers who are considering enrollment in a clinical trial. This approach is generally consistent with the practice that has been in effect since *ClinicalTrials.gov* was launched in 2000. This approach helps ensure that the existence of an NCT number for a specific clinical trial remains an indicator both that a publicly posted clinical trial has been registered and that the clinical trial information has gone through the quality control review process. Use of NCT numbers is required in certain submissions to FDA and in reports to NIH and other HHS agencies from relevant grantees and contractors as evidence that clinical trials have been publicly registered, as required by section 402(j) of the PHS Act, and by other stakeholders, including journal editors, as evidence of public disclosure of certain protocol information. Users searching *ClinicalTrials.gov* will be able to elect to include or exclude posted study records containing clinical trial information that has not concluded the quality control review process. In addition, because the quality control review process cannot ensure the veracity of the data submitted, all entries in *ClinicalTrials.gov* will carry a disclaimer to that effect.

The quality control review process will continue even after submitted information is posted, with a notice that the quality control review process has not concluded. Specifically, responsible parties must correct or address apparent errors, deficiencies, and/or inconsistencies within 15 calendar days (clinical trial registration information) or 25 calendar days (clinical trial results information) of notification sent by the Director. For example, if quality control review identifies two or more data elements within a clinical trial record that are internally inconsistent, the responsible party will be notified that submitted clinical trial information does not appear to meet specified quality review criteria, including the identity of the particular elements involved. When the responsible party submits revised clinical trial information or provides explanatory information that addresses the apparent errors, deficiencies, and/or inconsistencies, any revised information will be posted after the quality control review. Further, when all apparent errors, deficiencies, and/or inconsistencies have been addressed, the statement that the quality control review process for that clinical trial record has not concluded will be removed from the posted record. However, the information that was initially posted will appear in the archived history for that clinical trial entry, and the archived version would indicate that it had been posted with a notice. The electronic notification sent to the responsible party would inform responsible parties of these facts.

We further explain that the quality control review process consists of two sequential components as follows: (1) An automated system-based check followed by (2) a manual review. In the first component, the *ClinicalTrials.gov* system alerts responsible parties to machine-detectable errors in the data entered (*e.g.,* certain types of missing information that is required, certain types of impossible values, certain types of internally inconsistent data). The number of automated checks the system performs has increased over time as we have gained experience with the types of errors that occur and devised additional automated rules for detection. We will continue to refine the automated checks in order to assist submitters in detecting and minimizing errors, deficiencies, and inconsistencies in the information they are submitting. Following resolution of any errors identified by the automated system prior to submission, *ClinicalTrials.gov* staff then manually reviews data submissions to identify, based on detailed quality control review criteria, additional apparent errors, deficiencies, and/or inconsistencies not detected by the automated checks. As noted previously, if problems are identified during the manual review, an electronic notification will be sent to the responsible party, indicating that the submission contains apparent errors, deficiencies, and/or inconsistencies with a listing of the specific issues that were identified with a request for correction within 15 calendar days (clinical trial registration information) or 25 calendar days (clinical trial results information).

In the proposed rule, we detailed the steps taken to satisfy the pilot quality control project under section 402(j)(5)(C)(i) of the PHS Act that directed HHS to develop a process to help ensure that clinical trial results information submitted to *ClinicalTrials.gov* is non-promotional and is not false or misleading. The quality control study consisted of two parts as follows: (1) Review of the results of more than 4,500 clinical trials submitted under section 402(j)(3)(C) of the PHS Act after September 27, 2008; and (2) an initial validation study of the *ClinicalTrials.gov* results data bank with trial results reported in the published literature, conducted under contract by researchers at the Oregon Health Science University [Ref. 13].

Since publication of the NPRM, we have completed a third part of the QC pilot study: A validation study of the *ClinicalTrials.gov* results data bank with trial results reported in FDA review documents that are publicly available on the *Drugs@FDA* Web site, conducted under contract by researchers at The Dartmouth Institute for Health Policy and Clinical Practice [Ref. 111a]. The study determined that primary outcome descriptions for sampled trials with results available in both sources were generally consistent. However, other information could not be directly compared (*e.g.,* adverse events are reported per trial at *ClinicalTrials.gov*, but are sometimes aggregated across multiple trials on *Drugs@FDA* to summarize the overall adverse event profile of a particular product).

Given the limitations of, and differences in, the databases identified in this study and the findings from the other parts of the quality control study, we have determined that comparisons with external sources of information could not be used to validate results information submissions. Our experience reviewing submissions to date leads us to conclude that the most appropriate approach for implementing quality control procedures at *ClinicalTrials.gov* is to have all submissions undergo the two-stage quality control review process developed during the pilot study. This quality control review process focuses on the content within a study record and includes automated validation rules followed by a detailed, manual review of submitted information.

The quality control review process is conducted to help identify "apparent errors, deficiencies, and/or inconsistencies" in the submitted information. That process, however, cannot ensure that the submitted information is truthful and non-misleading. Therefore, compliance with the quality control review process, including the requirements set forth in § 11.64, does not constitute a legal defense to enforcement pursuant to section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)), section 303(f)(3) of the FD&C Act (21 U.S.C. 333(f)(3)), or any other Federal law. A provision has been added to § 11.64 of the final rule to clarify this point.

Section 11.64(b)(2) specifies the requirements for correcting errors identified by a responsible party. It is anticipated that responsible parties may become aware of needed corrections through their own reviews of submitted data or from other parties. We, therefore, define procedures similar to those in § 11.64(b)(1) for correcting or addressing such errors, including specifying the general timeline for corrections as not later than 15 calendar days (clinical trial registration information) or 25 calendar days (clinical trial results information) after the responsible party becomes aware of any such errors. In addition, for errors that are determined by the responsible party and the Director to be uncorrectable, information will be posted on the record regarding the uncorrectable information. As specified in § 11.64(b)(2)(ii), a responsible party's obligation to submit correction of errors will end on the date on which complete clinical trial results information has been submitted as specified in section 402(j)(3)(C) and 402(j)(3)(I) of the PHS Act or § 11.48, as applicable, and corrections have been made, or addressed, in response to any electronic notice received under § 11.64(b)(1). We also have clarified that for any clinical trials that are not subject to the clinical trial results information submission requirements, the obligation to correct errors ends on the date on which complete clinical trial registration information has been submitted as specified in section 402(j)(2)(A)(ii) of the PHS Act or § 11.28, as applicable, and corrections have been made in response to any electronic notice received under § 11.64(b)(1).

E. Subpart E—Potential Legal Consequences of Non-Compliance

1. § 11.66—What are potential legal consequences of not complying with the requirements of this part?

Overview of Proposal

Other than the requirement that a responsible party not submit false or misleading information and the associated notice of potential liabilities for doing so (see § 11.6), the proposed codified text did not describe the potential legal consequences of failing to comply with the requirements of the rule. Although we did include in the preamble to the proposed rule a general discussion of the statutory procedures and penalties related to non-compliance (79 FR 69570), we did not otherwise discuss in detail the legal ramifications of failure to comply with the requirements of section 402(j) of the PHS Act, including these regulations.

Comments and Response

As discussed in Section III.A above, we received a number of comments about enforcement of the rule. Within the context of the FDAAA Title VIII statutory enforcement provisions, commenters proposed that NIH and FDA take certain approaches to enforcing the section 402(j) requirements. Commenters proposed specific penalty structures, such as only penalizing the responsible party and not the institution and making all intentional violations criminal with mandatory prison sentences. They also proposed incentives, such as providing easier submission mechanisms and citable credit for shared data sets. As previously stated, the specifics of how and under what circumstances the agencies will seek to enforce section 402(j), including the requirements of this final rule, are beyond the scope of this rulemaking. We expect that the clarification of responsibilities and obligations in this final rule will lead to a high level of voluntary compliance with these requirements. However, we believe that it also is important that responsible parties be more fully aware of the procedures and penalties to which non-compliance could subject them. Therefore, although the procedures and penalties for non-compliance would be applicable regardless of whether they are included in the codified text, we have decided to add new § 11.66, which describes the potential legal consequences set forth in the FDAAA Title VIII enforcement provisions.

Final Rule

The final rule includes new Subpart E—Potential Legal Consequences of Non-compliance and *§ 11.66—What are potential legal consequences of not complying with the requirements of this part?* This new section describes potential civil or criminal actions, civil monetary penalty actions, and grant funding actions that may be taken because of responsible parties' failure to comply with Part 11. Not all potential legal consequences are included. For example, as discussed in relation to § 11.6, other federal laws also govern the veracity of information submitted to the Federal Government, such as 18 U.S.C. 1001 (making it a crime to make certain false statements to the executive, legislative, or judicial branch of the U.S. government). Accordingly, new § 11.66 should not be understood as describing the exclusive means of enforcement that the Government might undertake with respect to compliance with FDAAA Title VIII, including these regulations.

New § 11.66(a) describes certain non-compliant activities that can lead to civil or criminal judicial actions against the responsible parties. FDAAA Title VIII amended the FD&C Act by adding a new subsection 301(jj) (21 U.S.C. 331(jj)) to the prohibited acts provisions. New § 11.66(a)(1) describes that, under 301(jj)(1) of the FD&C Act, failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, or knowingly submitting a false certification under that section, is a prohibited act. Section 402(j)(5)(B) requires submissions of new drug applications under section 505 of the FD&C Act, premarket approval applications under section 515 or 520(m) of the FD&C Act, biologics license applications under section 351 of the PHS Act, or reports under section 510(k) of the FD&C Act to be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act have been met. The applicable requirements of section 402(j) now include the requirements in Part 11.

New § 11.66(a)(2) describes that failure to submit clinical trial information required under section 402(j) of the PHS Act is a prohibited act under section 301(jj)(2) of the FD&C Act. The clinical trial information required to be submitted under Part 11 is clinical trial information required under section 402(j).

New § 11.66(a)(3) describes that submission of clinical trial information under section 402(j) that is false or misleading is a prohibited act under section 301(jj)(3) of the FD&C Act. Section 11.6 specifically provides that information submitted by a responsible party under this part "shall not be false or misleading in any particular." This language in § 11.6 reflects the precise language of section 402(j)(5)(D) of the PHS Act, which is then incorporated by reference in section 301(jj)(3) of the FD&C Act's prohibited act section. Violating § 11.6 would thus be a prohibited act under section 301(jj)(3).

Judicial remedies for violations of section 301 of the FD&C Act include injunctions and criminal penalties. Under section 302 of the FD&C Act (21 U.S.C. 332), U.S. district courts have jurisdiction to restrain violations of section 301. Under section 303 of the FD&C Act persons who violate section 301 can be imprisoned or fined. Pursuant to 18 U.S.C. 3571, current generally applicable fines are (1) for individuals, up to $100,000 for a misdemeanor, up to $250,000 for a felony violation and (2) for organizations, up to $200,000 for a misdemeanor, up to $500,000 for a felony violation. Such remedies could be accomplished through judicial proceedings initiated by FDA and brought to court by the Department of Justice.

New section 11.66(b) describes generally that any person who violates section 301(jj) of the FD&C Act is subject to civil monetary penalties under section 303(f)(3) of the FD&C Act (21 U.S.C. 333(f)(3)). Under FDAAA Title VIII's addition of 303(f)(3) to the FD&C Act, a person who commits any of the prohibited acts described in section 301(jj)(1),(2), or (3) would be subject to a civil monetary penalty of "not more than $10,000 for all violations adjudicated in a single proceeding" (21 U.S.C. 333(f)(3)(A)). Under 402(j)(5)(C)(ii), if the Secretary determines that any clinical trial information was not submitted as required, or was false or misleading, the Secretary shall notify the responsible party and give them an opportunity to remedy the non-compliance within 30 days. As part of the civil monetary penalties provision, if the violation is not corrected within 30 days following such notification, the person is subject to an additional civil monetary penalty of "not more than $10,000 for each day of the violation" until the violation is corrected (21 U.S.C. 333(f)(3)(B)). With respect to the dollar amounts for the civil monetary penalties, separate laws provide for periodically adjusting for inflation the maximum civil monetary penalty amounts (the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Public Law 114–74)). FDA's procedures for administrative imposition of civil monetary penalties are in 21 CFR part 17.

New § 11.66(c) describes the FDAAA Title VIII provisions related to grant funding. Under section 402(j)(5)(A) of the PHS Act, if an applicable clinical trial is funded in whole or part by HHS, any required grant or progress report forms must include a certification that the responsible party has made all required registration and results submissions. If it is not verified that the required registration and results clinical trial information has been submitted for each applicable clinical trial for which a grantee is the responsible party, any remaining funding for a grant or funding for a future grant to such grantee will not be released. If the head of an HHS agency verifies that a grantee has not submitted such clinical trial information, the agency head will provide notice to the grantee of the non-compliance and allow the grantee 30 days to correct the non-compliance and submit the required clinical trial information. As with other matters, the head of the agency may delegate this authority to other agency officials. Registration and results information submissions required under Part 11 are required submissions for purposes of these grant funding provisions.

Although not included in § 11.66, there is a statutory provision that directs NIH to include notices in the registry and results data bank containing certain non-compliance information. Under section 402(j)(5)(E), these notices, including specified statements, alert the public to: Instances of failure to submit required information; submission of false or misleading information; penalties imposed, if any; whether the information has been corrected in the data bank; and, failure to register the primary and secondary outcomes.

F. Effective Date, Compliance Date, and Applicability of Requirements in This Part

Overview of Proposal

Section 402(j) of the PHS Act does not establish time periods for the effective date or compliance date of the rule, or the length of time between them. In the

NPRM, the effective date was 45 calendar days after the date on which the final rule is published (79 FR 69592). As of that date, the *ClinicalTrials.gov* system would be modified to allow responsible parties to comply with the rule. We further proposed that the compliance date would be 90 calendar days after the effective date (79 FR 69592), meaning that a responsible party would have until the compliance date of the rule to come into compliance with the requirements of the rule.

For applicable clinical trials, the NPRM also described in Section III.D how clinical trial records at the time of the effective date would be handled. For registration information, for information submitted on or after the effective date, the information would need to comply with the rule. For a trial ongoing as of the effective date, with registration information submitted before the effective date, the NPRM stated that the information would have to comply with § 11.28 of the rule by the compliance date. Under this proposal, responsible parties would have been required to revise and/or add registration information to comply with the rule. For an applicable clinical trial that reached its completion date prior to the effective date, the responsible party would not have been required to comply with the rule, but would have been expected to have provided registration information as required by section 402(j)(2)(A)(ii) of the PHS Act. The responsible party would also have been required to update any information necessary, consistent with section 402(j)(4)(C) of the PHS Act.

With respect to results information, section 402(j)(3)(D)(iv)(II) requires the Secretary to determine in rulemaking whether certain clinical trial information (*i.e.,* technical and non-technical summaries, full protocols, and other categories, as appropriate) ''should be required to be submitted for an applicable clinical trial for which the clinical trial information described in subparagraph (C) [basic results] is submitted to the registry and results data bank before the effective date of the regulations . . .'' The NPRM provided that the responsible parties for applicable clinical trials for which results information was submitted under section 402(j)(3)(C) of the PHS Act before the effective date would not be required to provide the results information specified in proposed § 11.48 of the rule. For an applicable clinical trial that reached its completion date prior to the effective date of the final rule, the proposal would have required the responsible party to submit all of the results information specified in proposed § 11.48 if the responsible party had not submitted results information under section 402(j)(3)(C) of the PHS Act prior to the effective date of the rule. For an applicable clinical trial with a completion date before the effective date and for which partial results were submitted prior to the effective date, but the remaining partial results were neither due nor submitted until on or after the effective date, the proposal would have required the responsible party to submit clinical trial results information under proposed § 11.48 for all outcome measures, including modifying the primary outcome measure(s) submitted before the effective date to be in accordance with the requirements specified in proposed § 11.48 (79 FR 69593). For applicable clinical trials completed before the effective date of products that are never approved, licensed, or cleared, results information would not have been required to be submitted. For applicable clinical trials completed before the effective date of unapproved, unlicensed, or cleared products that are subsequently approved, licensed, or cleared after the effective date, it was proposed that results information would be due by the earlier of 1 year after completion of the trial or 30 calendar days after FDA approval, licensure, or clearance of the studied drug or device (79 FR 69594).

The NPRM addressed how voluntary submissions under § 11.60 (for applicable clinical trials for which registration clinical trial information were not required to be submitted or clinical trials of FDA-regulated drugs or devices that are not applicable clinical trials) would be handled at the time of the effective date. It was proposed that voluntary submissions made on or after the effective date must comply with the final rule, regardless of trial completion date (79 FR 69594).

The NPRM also addressed how updates and corrections to submitted clinical trial information (§§ 11.64 and 11.66) would be handled:

- For clinical trial registration or clinical trial results information due on or after the effective date, the responsible party would be required to comply with proposed § 11.64 for updating the information.
- For clinical trial information due prior to the effective date, the responsible party would be required only to update the information in accordance with section 402(j)(4)(C) of the PHS Act.
- For an applicable clinical trial that reaches its completion date prior to the effective date, but for which results information are due after the effective date, the responsible party would be required to update *registration* information according to section 402(j)(2)(A)(ii) of the PHS Act, but update *results* information (submitted after the effective date) according to proposed § 11.64.
- For an applicable clinical trial that is registered in accordance with section 402(j)(2) of the PHS Act but is ongoing as of the effective date, because the responsible party would be required to submit registration information consistent with proposed § 11.28 by the compliance date, updates would also be required according to proposed § 11.64.

The NPRM also stated that if the responsible party is aware of clinical trial information that contains errors, the responsible party would be required to submit corrections according to § 11.66, regardless of when that information was originally submitted (79 FR 69594).

Comments and Response

Commenters expressed opinions on a variety of points related to the proposed effective and compliance dates of the rule. Regarding the timeline, commenters suggested an effective date later than the proposed 45 calendar days after the rule's publication, such as 90 calendar days after the rule's publication. Similarly, commenters suggested an compliance date later than the proposed 90 calendar days after the effective date, such as 180 calendar days after the effective date. Others supported a phased implementation of the rule's requirements to permit increased institutional readiness and to allow HHS to address practical compliance barriers that might arise during the early stages of the rule's implementation, including the updating of *ClinicalTrials.gov* to accommodate clinical trial information from new types of trials.

First, we have extended the effective date from 45 calendar days to provide at least 120 calendar days after filing for public inspection of this rule by the Office of the Federal Register. However, but the compliance date will remain 90 calendar days after the effective date. This extended effective date will allow responsible parties subject to the rule more time to review the new requirements and prepare, update, and reconfigure their institutional operations and databases appropriately. It will also allow *ClinicalTrials.gov* additional time to ensure system readiness by the effective date (*e.g.,* update the PRS online forms to incorporate the new data elements, update the automated validation rules, and revise the user guide and other documentation to reflect the requirements of the final rule). While the period of time between the effective date and compliance date remains as proposed, responsible parties can use the longer time between publication of the rule and the effective date to prepare for any submissions needed to comply with the final rule.

Commenters responded to the Agency's proposals on how clinical trial records at the time of the effective date of the rule would be handled. They disagreed with the approach to require results information for all outcome measures to comply with the rule in situations for which results information for primary outcome measures were submitted prior to the effective date, but results information for other measures are neither due nor submitted until on or after the effective date. Commenters suggested that the NPRM proposal, which would require updating the previously submitted information, might be burdensome, and researchers may not have designed or budgeted for such updates.

Others opposed the requirement to comply with the rule when a trial was completed before the effective date and, regardless of its due date, results information was not submitted prior to the effective date. They highlighted burden and additional workload as reasons for their opposition. One commenter opposed application of the rule to ongoing trials, suggesting that it disrupts the investment-backed expectations in place during early development of studied products.

Other commenters outlined alternatives to the proposal, including that new registration provisions only apply to trials registered after the effective date, and that new results provisions only apply to new results posted after the effective date, and to clinical trials with completion dates after the effective date. Another commenter suggested the burden caused by the proposal when the First Subject First Visit or Primary Completion Date is before the effective date—reporting on these studies would require reworking to accommodate the new criteria. This commenter noted a particular burden on small entities and suggested that the rule only apply to studies with First Subject First Visit or Primary Completion Dates after the effective date. As mentioned above, we have simplified the requirements for information submission during the transition, and this is discussed in more detail below.

One commenter suggested that applying regulations retroactively does not comport with typical legal standards of due process that favor prospective, as opposed to retroactive, application. Another commenter noted that if NIH does apply the rule retroactively to previously registered trials, responsible parties may need more time to address updates. We have considered the effects of the requirements in the final rule and do not believe that there are any impermissible retroactive effects that flow from the final rule. We believe that the revised approach being adopted alleviates the concerns expressed by commenters in this regard.

While we received no comments suggesting that the handling of clinical trial records on and immediately after the effective date be made explicit in the regulatory text, we did receive comments indicating that the rules are confusing. To resolve that general concern, we have restructured the requirements for which applicable clinical trials must be registered, whether results information submission is required for a particular applicable clinical trial, and whether the applicable registration and results information submission requirements are those specified in section 402(j) of the PHS Act or are those specified in these regulations. In making these changes, our aim is to be as clear as possible about the obligations of responsible parties.

Final Rule

The final rule differs from the proposal the NPRM in two important ways. First, we have extended the effective date from 45 calendar days to at least 120 calendar days after filing for public inspection of this rule by the Office of the Federal Register. However, the compliance date will remain the same, at 90 calendar days after the effective date. Second, the rule simplifies the process for determining which applicable clinical trials and information are subject to the rule's reporting requirements. Specifically, the registration requirements that apply to an applicable clinical trial are determined by the date on which the trial is initiated (*i.e.*, the actual study start date as defined in § 11.10(b)(16)), and the results information submission requirements that apply to an applicable clinical trial are determined by the date on which the trial reaches its actual primary completion date. We believe that this framework provides a logical approach to registering and submitting results information, in that it relies on what are, in the simplest terms, and for purposes of section 402(j) of the PHS Act and these regulations, the start date and the primary completion date of a trial.

Under this approach, the registration and results information submission requirements that apply to any given applicable clinical trial also depend on whether the trial is of an approved, licensed, or cleared product, or an unapproved, unlicensed, or uncleared product. We have reconsidered the approach described in the NPRM (79 FR 69593) with respect to determining whether an applicable trial involves an approved, licensed, or cleared product, or whether it involves an unapproved, unlicensed, or uncleared product. For purposes of this final rule, the marketing status of a product will be determined based on its marketing status on the primary completion date. Thus, if a drug product (including a biological product) or a device product is approved, licensed, or cleared for any use as of the primary completion date, we will consider that applicable clinical trial to be a trial of an approved, licensed, or cleared product. Similarly, if a drug product (including a biological product) or a device product is unapproved, unlicensed, or uncleared for any use as of the primary completion date, regardless of whether it is later approved, licensed, or cleared, we will consider that applicable clinical trial to be a trial of an unapproved, unlicensed, or uncleared product.

As a result of this interpretation, whether results information submission is required for an applicable clinical trial of an unapproved, unlicensed, or uncleared product depends on whether the primary completion date for that trial falls before or after the effective date of the regulations. If it falls before the effective date, then no results information is required to be submitted for that applicable clinical trial, regardless of whether the product studied in that clinical trial is later approved, licensed, or cleared. If the primary completion date is after the effective date of the final rule, then results information submission is required as specified in the final rule.

We recognize that there are responsible parties who submitted results information pursuant to the provisions in sections 402(j)(3)(C) and (E) for applicable clinical trials of products that were not approved, licensed, or cleared at the time the trial was ongoing, but which were approved after the primary completion date. Notwithstanding the fact that, under the interpretation in the final rule, results information for these trials was not required to be submitted, we do not consider the results information for these trials to have been submitted pursuant to section 402(j)(4)(A). Although the previously submitted information will remain in the PRS system and will be publicly available, it is not subject to either the provisions of § 11.60 regarding voluntary submissions or the requirements in § 11.64 with respect to updates and corrections of information. The Agency does, however, encourage responsible parties to update such previously submitted results information and would not consider such updates to be subject to the voluntary submission requirements in § 11.60.

The applicable registration and results information submission requirements are summarized in the following table:

APPLICABILITY OF REQUIREMENTS IN 42 CFR PART 11

Initiation date	Primary completion date	Registration information submission required?		Results information submission required?	
		Approved, licensed, or cleared products	Unapproved, unlicensed, or uncleared products	Approved, licensed, or cleared products	Unapproved, unlicensed, or uncleared products
On or before September 27, 2007	After December 26, 2007 and before Effective Date of Final Rule.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in section 402(j)(3)(C) and section 402(j)(3)(I) of the PHS Act.	No.
After September 27, 2007 and before the Effective Date of the Final Rule.	Before Effective Date of Final Rule.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in section 402(j)(3)(C) and section 402(j)(3)(I) of the PHS Act.	No.
After September 27, 2007 and before Effective Date of Final Rule.	On or after Effective Date of Final Rule.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in section 402(j)(2)(A)(ii) of the PHS Act.	Yes, as specified in 42 CFR part 11.	Yes, as specified in 42 CFR part 11.
On or after Effective Date of Final Rule	On or after Effective Date of Final Rule.	Yes, as specified in 42 CFR part 11.	Yes, as specified in 42 CFR part 11.	Yes, as specified in 42 CFR part 11.	Yes, as specified in 42 CFR part 11.

The table above does not apply to voluntary submissions under § 402(j)(4)(A) of the PHS Act and § 11.60. The registration and results information submission requirements for the voluntary submission of clinical trial information are addressed in § 11.60.

We recognize that there will be some situations that arise in the months leading up to and following the effective date where a responsible party's obligations may shift depending on a variety of factors. For example, there may be a small number of applicable clinical trials for which the study start date (*i.e.*, the date of initiation) changes after the trial is registered and that that change may result in a shift in the registration and/or results information submission requirements for that applicable clinical trial. For example, if a responsible party initially registered an applicable clinical trial two months before the effective date of the final rule and entered an estimated study start date that fell one month before the effective date of the final rule, the responsible party's understanding at the time of registration would be that it would need to submit registration information as specified in section 402(j)(2)(A)(ii) of the PHS Act. However, if the trial is not initiated until after the effective date of the final rule, the responsible party will be required to comply with the registration provisions as specified in the final rule and to update the registration information for that applicable clinical trial. In a situation such as this, we would expect clinical trial registration information to be updated promptly, but in any case no later than as required under § 11.64(a) of the final rule. We note that in this scenario the responsible party will have been on notice since the publication date of the final rule both that the registration requirements will be changing as of the effective date and what those changes will be.

Similarly, if a responsible party initially registered an applicable clinical trial two months before the effective date of the final rule and entered an estimated study start date that fell one month after the effective date of the final rule, the responsible party's understanding at the time of registration would be that it would need to submit registration information as specified in the final rule (although we note that, because of the work needed to update the *ClinicalTrials.gov* data bank to accommodate the changes in the final rule, it may not be possible to enter information required as specified in the final rule prior to the effective date). However, if the applicable clinical trial actually was initiated one week before the effective date of the final rule, the trial would instead be subject to the registration requirements as specified in section 402(j)(2)(A)(ii) of the PHS Act and not the final rule.

Further, it is our understanding that, because of the complexities of how clinical research activities are managed at larger institutions, in some situations an applicable clinical trial might have been initiated but the individual who is responsible for submitting registration information regarding that trial might not have received notice of that initiation. If this scenario were to occur shortly after the effective date of the final rule, it is possible that the trial would be registered under the assumption that the requirements in the final rule apply and, therefore, more clinical trial information would be submitted than would be required. In this situation, the responsible party would not be required to update that additional registration information (although the information itself would remain available in the PRS system).

We also recognize that because a responsible party has 21 days after initiation in which to register an applicable clinical trial, it is possible that a trial might be initiated before the effective date of the final rule but the responsible party might not submit registration information for it until after the effective date of the final rule. In this situation, notwithstanding the fact that the registration information for that applicable clinical trial was submitted after the effective date of the final rule, the Responsible Party would only be required to submit registration information as specified in section 402(j)(2)(A)(ii) of the PHS Act, not the final rule.

We appreciate that the possibility that situations such as these may arise will be of concern to affected responsible parties, and we are committed to assisting them in understanding their responsibilities and determining which requirements apply to particular applicable clinical trials. We would like to emphasize, however, that it has been clear since the proposed rule was issued in 2014 (and, in our view, since the enactment of FDAAA, with both its requirement that the rulemaking address the issue of results information submission and the provision that the Secretary may modify the registration requirements) that changes to the registration and results information submission requirements were both possible and highly probable.

While we believe that the NPRM provided a logical approach for handling records in transition, we understand that the approach might have been confusing to responsible parties. We believe that these changes will address the concerns of many commenters, such as those who did not believe primary outcome measures should have to be resubmitted when secondary outcome measures were due and submitted after the effective date. This change is simpler and clearer for those who were compliant under section 402(j) of the PHS Act. In addition, with the change to a later effective date, responsible parties who are subject to the registration and/or results information submission requirements in the final rule will have more time to plan accordingly.

V. Regulatory Impact Statement

The Agency has examined the impacts of this final rule under Executive Order 12866, Regulatory Planning and Review, Executive Order 13563, Improving Regulation and Regulatory Review, the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132, Federalism. Executive Order 12866, as amended by Executive Order 13563, directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any single year). The Agency estimates that the total cost of the requirements to regulated entities is approximately $59.6 million annually. We anticipate the potential for significant scientific and public health benefits, in the form of improvements in clinical trial designs, human subjects' protections, and improved evidence base to inform product development and clinical care. In addition, enhanced access to information about clinical trials may increase public trust in the research enterprise. We estimate that this rule is not an economically significant regulatory action as defined by Executive Order 12866. Because of the interest in this rule among regulated entities and others involved in conducting or using the results of clinical trials, we have, nevertheless, prepared an analysis that, to the best of our ability, estimates the costs and benefits of this rule. The RFA requires agencies to analyze regulatory options that would minimize any significant impact of a rule on a substantial number of small entities. The rule is estimated to impose costs of approximately $17,907 per applicable clinical trial (see Table 1 and Section V.G for additional information). Based on the RFA analysis (see Section V.G), we estimated that most small entities would be expected to be responsible for no more than one applicable clinical trial per year and that the per applicable trial cost to them would in general represent a small fraction of their revenues. This analysis forms the basis of the Agency's certification that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires, among other things, that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year" (2 U.S.C. 1352(a)). The current threshold, adjusted for inflation using the 2015 Implicit Price Deflator for the Gross Domestic Product, is $146 million. The Agency does not expect this rule to result in any 1-year expenditure that would meet or exceed this amount. As explained above, however, the Agency has conducted an analysis of the costs that could result from this rule.

Executive Order 13132 (Federalism) establishes certain requirements that an Agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

A. Comments and Response

Commenters responded to the economic analysis in the NPRM of the estimates of the costs and benefits of the rule. While some commenters found the analysis appropriate overall and considered a 40 hour estimate for results information submission to be accurate, other commenters suggested that the time estimates used to calculate registration, results, and updates burden were lower than they should be. Some argued that the burden of entering information into the database is greater for smaller research institutions because, unlike larger research organizations, they are less likely to have dedicated and trained personnel to manage clinical trial information reporting. Others suggested the rule will be equally burdensome to small and large organizations. We recognize that some members of the regulated community may spend more hours than others to develop, process, and maintain clinical trial records. However, we believe our estimates of 8 hours for registration information, 40 hours for results information and 16 hours for updates of information are a reasonable representation of the overall average time required to complete all registration and results requirements by all respondents.

Commenters also suggested that *ClinicalTrials.gov* harmonize its clinical trial reporting requirements with existing international regulations in order to decrease the burden on institutions. It was suggested that reporting unique numbers of individuals with adverse events by organ system differs from the EU reporting standards and increases the burden of the rule. In consideration of the commenters' concerns, the final rule no longer requires the reporting of numbers of people with adverse events at the organ system level. We anticipate that this change will decrease the burden of the rule.

One commenter suggested that the rule would also have an economic impact on biopharmaceutical development because of competitive harms associated with premature disclosure of confidential commercial information. As discussed in Section III.B of this preamble and § 11.44, this rule requires only summary level results information to be submitted, and it allows for delayed submission with certification in order to minimize any perceived competitive disadvantages for unapproved, unlicensed, or uncleared products (see § 11.44(b) and (c)) and delayed posting of registration information for unapproved or uncleared device products (see § 11.35(b)(2)(i)). Submission of clinical trial results information for applicable clinical trials of approved, licensed, or cleared products and applicable clinical trials of unapproved, unlicensed, or uncleared products, according to deadlines established by the final rule, ensures consistent and timely public access to comprehensive summary results for all applicable clinical trials. Furthermore, we are not persuaded that economic harms will result from the public posting of the required data elements.

Commenters also suggested that the cost estimates understated the burden associated with bringing previously submitted registration information into compliance with the final rule. One commenter suggested that the cost of compliance will not go down over time, while another suggested that in order to decrease this burden, the rule should only apply to those trials that had their First Subject First Visit or Primary Completion Date after the effective date of the rule. In consideration of commenters' concerns, the final rule eliminates virtually all additional burden associated with updating previously submitted trial information by requiring only registration as specified in the final rule for applicable clinical trials for which the date of initiation is after the effective date of the final rule and by only requiring results information submission as specified in the final rule for applicable clinical trials that reach their primary completion date after the effective date of the final rule. In light of these changes, which are discussed in more detail in Section IV.F of this preamble, there are very few applicable clinical trials registered or submitted partial results prior to the effective date of the final rule that will need to be updated as a consequence of the rule. As such, we expect the burden associated with such situations to be minimal because they will arise relatively infrequently. In addition, we anticipate that the occurrence of such situations will decrease over the next three years because, ultimately, there will be very few ongoing applicable clinical trials that were initially registered prior to the effective date of the final rule.

Another commenter suggested that the correction procedures proposed in § 11.66 could cause further economic burden because they thought that no clear distinction in the definitions of errors and falsifications was provided, which they said could lead to unnecessary and costly preemptive actions by the responsible party. The final rule no longer distinguishes between different types of errors (see § 11.64), and, thus, the potential economic burden of differentiating the type of error has been eliminated.

Commenters also suggested that the Agency should calculate actual burden and include other costs such as reprograming of institutional systems, increased medical review, and management oversight. They suggested that we had not sufficiently considered the costs associated with activities carried out by organizations that may invest substantial resources to avoid the negative consequences of violating the legal and regulatory requirements, *e.g.*, loss of federal grant support and/or monetary penalties. We agree that our cost estimate did not attempt to isolate the cost and burden that an institution as a whole might absorb in order to facilitate and monitor compliance among clinical investigators subject to the rule who are employed by the institution. Because overhead costs (*i.e.*, costs not related to direct labor or direct materials) varies among different industries and occupations, we attempted to approximate those overhead costs by doubling the average hourly wages in the personnel cost calculations. We took this approach in part because the cost of this rule is likely to vary significantly among institutions and organizations due to differences in institution's sizes, frequency of clinical trials performed per year and variation in the need to update or create information technology tools or application used to support clinical trial registration and results information submission and also because of the lack of data on the cost of institutional compliance. Nonetheless, in response to public comments, we have developed a separate estimate of the costs that institutions may assume in order to facilitate and monitor compliance among employees with responsibilities under the rule. The estimate is described in Section E below.

Commenters suggested that the Agency should allow financial burden of registration and results reporting to be covered as a direct cost in grants, whether incurred by the investigator or shared with a central administration unit. The Agency has previously clarified for NIH awardees that "[g]iven the nature of registration and result information report requirement and that the project staff will generally be in the best position to submit and maintain these data, the costs of compliance with section 402(j) of the PHS Act will be generally allowable as direct charges to NIH grants. While it is expected that these costs will be covered by the funds provided with the grant, administrative supplements could also be considered" [Ref. 112].

B. The Final Rule

The final rule codifies in federal regulation the provisions for the mandatory registration and submission of results information for applicable clinical trials to *ClinicalTrials.gov*, as required by section 402(j) of the PHS Act. This rule both clarifies the existing statutory requirements for submission of registration and results information, including adverse events information, and implements the expansion of the registry and results data bank by rulemaking as required by section 402(j)(3)(D) of the PHS Act.

C. Need for the Final Rule

The Agency is promulgating this rule to fulfill the requirements of section 402(j) of PHS Act in a manner that will provide broad public access to pertinent clinical trial registration and results information. Section 402(j)(2)(A)(i) of the PHS Act requires the Secretary to expand the clinical trials registry data bank with respect to clinical trial information to "enhance patient enrollment and provide a mechanism to track subsequent progress" of the clinical trials. Sections 402(j)(3)(B) and 402(j)(3)(C) of the PHS Act instruct the Secretary to expand the clinical registry data bank not later than 1 year after enactment of FDAAA to include the results information specified in section 402(j)(3)(C) for certain applicable clinical trials. Section 402(j) of the PHS Act also requires responsible parties to submit to the expanded data bank specified registration information (*i.e.*, descriptive information, recruitment information, location information, and administrative information) summarizing key aspects of applicable clinical trials that are subject to the law and specified results information describing the outcomes of applicable clinical trials for which the drugs or devices under study have been approved, cleared, or licensed by FDA. Section 402(j) of the PHS Act further establishes deadlines by which such information must be submitted and establishes penalties for non-compliance. This final rule implements the statutory requirements and clarifies the Agency's interpretation of them. It explains the meaning of terms defined in the section 402(j) of the PHS Act (*e.g.*, responsible party and applicable clinical trial) and of several data elements that are required to be submitted to the data bank (*e.g.*, study design, eligibility criteria). It also exercises the authority given to the Secretary in section 402(j)(2)(iii) of the PHS Act to modify by regulation the requirements for clinical trial registration information. This final rule specifies several modifications to the clinical trial registration information that the Agency believes meet the statutory criteria of improving and not reducing the statutorily specified clinical trial registration information.

In addition, this rule is necessary to implement provisions of section 402(j) of the PHS Act that are specifically required to be addressed by regulation. Section 402(j)(3)(I) of the PHS Act, requires the Secretary to determine by regulation the "best method" for including in the registry and results data bank appropriate results information on serious adverse and other adverse events collected for certain applicable clinical trials. Section 402(j)(3)(D) of the PHS Act requires, among other things, the Secretary to further expand the registry and results data bank through rulemaking to "provide more complete results information and to enhance patient access to and understanding of the results of clinical trials." Section 402(j)(3)(D) of the PHS Act specifies several topics that the rule is to address, including whether to require the submission of results information for applicable clinical trials of drugs and devices that have not been approved, licensed, or cleared by FDA; whether technical or lay summaries of a clinical trial can be included in the data bank without being misleading or promotional; and whether to require responsible parties to submit the protocol or "such information on the protocol . . . as may be necessary to help evaluate the results of the trial." This rule addresses each of these topics and others specified in section 402(j) of the PHS Act.

D. Benefits of the Final Rule

As discussed in Section I of this preamble, the overarching aim of the final rule is to provide public access to a standardized set of information describing the conduct and results of certain clinical trials of FDA-regulated drugs (including biological products) and devices. Access to clinical trial information has significant scientific, and public health benefits, which we describe in Section I. These benefits accrue to potential and enrolled clinical trial participants, clinical researchers, systematic reviewers, disease and patient advocacy groups, regulators, drug and device manufacturers, healthcare providers, patients and their family members. Public access to clinical trial information can help patients find trials for which they might be eligible, enhance the design of clinical trials and prevent duplication of unsuccessful or unsafe trials, improve the evidence base that informs clinical care, increase the efficiency of drug and device development processes, improve clinical research practice, and build public trust in clinical research.

Access to clinical trial information assists individuals in finding trials in which they may be eligible to enroll. It can help people in making more informed decisions about participating in a clinical trial by providing them and their care providers with information about the results of a broader set of clinical trials of various interventions that have been studied for a disease or condition of interest. The highly structured data and search engine allows members of the public to search for trials for which they may be eligible [Ref. 19]. It also enables third parties to use the information describing the clinical trial to meet other specific needs [Ref. 35], such as reformatting the data for constituents of various patient advocacy groups (*e.g.*, patients with breast cancer) [Ref. 36], data mining for associations among interventions and diseases studied worldwide, and for use in semi-automated data collection for conducting critical appraisals and systematic reviews to support evidence-based medicine. For example, while *ClinicalTrials.gov* does not itself match potential participants with relevant trials, the rule ensures the timely posting of registration information about trials currently enrolling participants. This information is used by third parties to provide matching services that help patients find trials that might be appropriate for them.

Increased clinical trial transparency has the potential to drive scientific progress by informing future research, identifying knowledge gaps and opportunities, improving study designs, and preventing replication of unsuccessful trials and initiation of unsafe trials. Accessibility of clinical trial information may accelerate the drug discovery and development process by reducing redundancies and facilitating the identification and validation of new drug targets or surrogate endpoints, and it allows for improved understanding of the safety and efficacy of new therapies. The information provides a more robust evidence base for new research, which reduces systematic bias and leads to better science. Strengthening the evidence base also maximizes returns on the contributions of clinical trial participants as well as the time and financial investments of investigators, study funders, and sponsors.

Access to clinical trial information enables IRBs [Ref. 25], researchers, funding agencies, systematic reviewers [Ref. 26, 27], bioethicists [Ref. 28], science and public policy makers [Ref. 29], and others to see the landscape of trials on a given topic, by a particular funder, by geography [Ref. 30], by population [Ref. 9], or other relevant criteria. Providing these users with such a capability informs their judgments about the potential value of new trials. It also helps ensure that assessments of the risks and benefits of a potential intervention for a particular use reflect the totality of evidence from all prior trials. Such information also enhances scientific and financial accountability of sponsors. Landscape analyses such as these also provide feedback and insights for the clinical research community, by informing the design and analysis of future trials [Ref. 11, 31, 32].

Access to clinical trial results information helps fill substantial gaps in the database left by the non-publication (or very delayed publication) of a substantial portion of clinical trials in the medical literature [Ref. 42, 43]. Access to results from clinical trials of unapproved, uncleared, or unlicensed products is expected to alleviate the concerns regarding bias in the literature and selective publication. The complete set of results for all primary and secondary outcome measures supplements the more limited set of results data found in the published literature [Ref. 13, 37]. The availability of results information will help prevent the evidence base that is the foundation of systematic reviews and clinical practice guidelines from being skewed.

The availability of results information for trials of unapproved products may inform the assessment of risks and benefits that potential participants might face in subsequent studies of those same or similar products; it may also contribute to the overall assessments that are made of similar marketed products [Ref. 46]. Trials of products that are unapproved, unlicensed, and uncleared are unlikely to be published if the results of these trials are insufficient to support applications for product approvals (*e.g.*, because the study resulted in negative findings or was inadequately designed or executed).

Clinical trials are expensive to initiate and carry out, and they are a significant national investment. Phase 2, 3, and 4 clinical trials cost on average, $13 million, $20 million, and $20 million respectively [Ref. 113], and it takes an average of $1.4 billion in clinical trial costs to develop 1 new compound [Ref. 114]. In FY 2016, NIH invested an estimated $3.3 billion in clinical trials and supportive activities [Ref. 115]. Access to more complete information about clinical trials helps conserve resources and, for federally funding trials, optimize the public investment in research. It helps avoid a suboptimal return on the financial resources invested by study funders and sponsors [Ref. 47] and can reduce costs by minimizing redundant trials.

Finally, another benefit of the rule is that it helps individual investigators, the clinical trial enterprise, and society as a whole fulfill an ethical obligation to trial participants. Individuals participate in clinical trials with the understanding that the research will contribute to the expansion of knowledge pertaining to human health. When trial information is withheld from public scrutiny and evaluation, the interpretation of the data and the public's trust in the research may be compromised. The rule helps to further the goal of ensuring that participation in research leads to accountability via the public reporting of information. The importance of trust in clinical research and public trust in the enterprise is promoted when we establish a public record of the trials in which people participate.

E. Costs Associated With the Final Rule

The costs associated with the final rule consist of the time and effort necessary for responsible parties to comply with the rule requirements to register applicable clinical trials; submit specified results information (including adverse event information); update and correct submitted registration and results information, as needed; submit certifications and/or extension requests to delay the deadline for submitting results information; submit information describing expanded access programs for drugs studied in an applicable clinical trial, and request waivers to any of the requirements for results information submission. We do not intend this rule to cause responsible parties to collect any information that was not already intended to be collected during the clinical trial, nor do we intend this rule to cause responsible parties to analyze such information in ways that were not intended under the protocol or the associated SAP. Rather, the rule specifies those elements of the collected results information that must be submitted to the data bank and the format in which that information must be submitted.

The calculations below present our estimates of the time and cost associated with meeting the information submission requirements of the final rule, including the burden associated with assembling the required information, formatting the information for submission, submitting it to the data bank, and correcting or updating it over time. The calculations break out the estimated annual costs associated with: (1) Registering a trial; (2) submitting results information; (3) submitting certifications, extension requests and appeals to delay the results information submission deadline; (4) submitting clinical trial information that is triggered by a voluntary submission; and, (5) creating expanded access records for drugs studied in an applicable clinical trial. The estimates include the costs associated with updating submitted information and with correcting errors detected by NIH. These are shown in the table below and, in the text below the table in Sections 1–5, we described these costs in more detail. We also estimate the costs of compliance to institutions that elect to devote resources to help investigators in their institutions who are subject to the rule to comply with its requirements. These additional resources mainly involve the hiring or reassignment of personnel to support the submission of registration and results information submission to *ClinicalTrials.gov*. The approach we took to estimate these costs is described below in Section 6. In the NPRM, we estimated cost of this final rule to be $32 million. Our higher estimate of $59.6 million is largely due to the more detailed consideration of costs that organizations may incur to ensure compliance on the part of responsible parties they employ.

1. Registration of Applicable Clinical Trials

To estimate the costs of trial registration, we first estimated the number of applicable clinical trials that would be initiated in a given year and be subject to the provisions of this final rule. Using the approach described below, we estimate that a total of 7,400 applicable clinical trials of drug products (including biological products) and device products per year would be subject to the registration requirement of this final rule. This estimate is based on information from FDA indicating that it receives approximately 5,150 clinical trial protocol submissions annually for applicable clinical trials (76 FR 256). This figure includes protocol submissions to CDER, CBER, and CDRH; it does not include clinical trials that were not conducted under an IND or IDE. To estimate the number of such clinical trials, we examined the number of clinical trials registered with *ClinicalTrials.gov* that appear to meet the criteria for an applicable clinical trial but do not appear to have been conducted under an IND or IDE, *e.g.*, because they are exempt from the requirement to submit an IND or IDE. We found approximately 1,700 and 2,000 such clinical trials in 2012 and 2013, respectively. We increased this figure to 2,250 to accommodate further growth in the number of such clinical trials that would be registered following publication of the final rule. The sum of these figures (*i.e.*, 5,150 plus 2,250 equals 7,400) provides an estimate of the number of applicable clinical trials that will be subject to the registration requirement of this final rule each year.

To calculate the burden associated with registering 7,400 clinical trials, we estimated the time required to submit complete clinical trial registration information for an applicable clinical trial. We estimate this time to be 8 hours, including time to extract information from the study protocol, reformat it, and submit it to *ClinicalTrials.gov*. This figure accounts for the estimated time needed to submit the 5 additional data elements that will be required by this final rule. Applying this time estimate to the estimated number of applicable clinical trials yields a burden of 59,200 hours per year for registering applicable clinical trials. Based on our previous experience, we estimate that each registration record will be updated an average of eight times during the course of the study (*e.g.*, to reflect changes in the conduct of the clinical trial, additions of investigational sites, recruitment status updates). Although clinical trials of long duration and with multiple sites will likely submit more updates during the course of the trial, we have found that many applicable clinical trials have a relatively short duration and a limited number of study sites, which lowers the average per clinical trial. The time required for subsequent updates of clinical trial registration information is expected to be significantly less than for the original registration as less information must be provided) and is estimated to be 2 hours per update, resulting in a total of 16 hours of additional time attributed to updates per trial. Using these figures, we calculated the total annual hour burden for updates to clinical trial registration information for all applicable clinical trials to be 118,400 hours. Combining this figure with the estimated time for initial registrations (59,200 hours) yields an estimate of the total hour burden associated with the submission and updating of clinical trial registration information of 177,600 hours per year. These estimates include the time involved in addressing any issues identified during quality control review of submitted registration information.

To calculate the cost of registration, we examined May 2015 data from the U.S. Bureau of Labor Statistics on the average wages of life, physical, and social science workers in the pharmaceuticals and medicine manufacturing and medical scientists (except epidemiologists) also working in the pharmaceutical and medicine manufacturing industries. During the time we have operated *ClinicalTrials.gov*, we have found that this task is generally performed by junior-level researchers or administrative staff. For purposes of this estimate, we used an average hourly wage rate of $36.02, which is the average wage of life, physical, and social science workers in the pharmaceuticals and medicine manufacturing industries and is significantly higher than the median wage of other administrative staff in those sectors who are typically tasked with submitting registration information to *ClinicalTrials.gov*. Because overhead costs vary among different industries and organizations, we approximate overhead costs by doubling the average hourly wages (to $72.04 per hour). Using this adjusted wage figure, we calculated an estimated total annual cost of registration under the final rule, including updates over the course of a clinical trial, of $12,794,304 (Table 1). This figure represents an incremental increase of $533,096 per year above the estimated cost of registration prior to the rule.

2. Results Information Submission

To estimate the burden associated with submission of clinical trial results information, we started with the premise that every clinical trial required to register in a given year would be required subsequently to submit results information. The statute requires results information submission for all applicable clinical trials that study drugs (including biological products) or devices that are approved, cleared, or licensed by FDA. The rule requires, in addition, the submission of clinical results information for applicable clinical trials of drug products (including biological products) and device products that are not approved, cleared, or licensed by FDA. We, therefore, estimate the burden associated with results information submission for a total of 7,400 applicable clinical trials of drug products (including biological products) and device products per year, recognizing that in most cases, such clinical trial results information will not be submitted in the same year as the associated clinical trial registration information but in accordance with the deadlines specified in § 11.44. We expect, however, that on average the number of clinical trials for which clinical trial results information is submitted in any given year will approximate the number of new trials for which clinical trial registration information is submitted.

To estimate an average amount of time required to submit clinical trial results information, we reviewed a variety of data sources, including publicly available information from various organizations about results information submission times [Ref. 116], comments made at the April 2009 public meeting [Ref. 64], responses to the burden estimates included in the current and previous OMB clearance documents (77 FR 22579, Apr. 16, 2012; 73 FR 58972, Oct. 8, 2008), feedback from respondents who tested preliminary versions of the data entry system during the summer of 2008, and feedback from those submitting data to the existing *ClinicalTrials.gov* system. These sources contain a wide-range of estimates, from as little as 6 hours to as long as 60 hours. We believe the differences in these estimates reflect a number of factors, including the significant variation in the complexity of applicable clinical trials, in terms of the study design, number of outcome measures (primary and secondary), statistical analyses, and adverse event information. The estimates also reflect differences in the responsible party's familiarity with the clinical trial results information and the *ClinicalTrials.gov* submission process and the time they attribute to assembling the information for submission. Shorter estimates may be indicative of situations in which the responsible party already has assembled (and analyzed) the clinical trial results information for purposes of preparing a journal article or other summary report, while longer estimates may assume the clinical trial results information needs to be calculated and compiled. We expect that, in most situations, the responsible party would have ready access to the necessary information because it is information that the clinical trial is conducted to collect and analyze (*i.e.*, the information for submission would have been collected during the trial, as specified in the protocol). Nevertheless, for purposes of this analysis, we selected an average time of 40 hours for initial submission of clinical trial results information, which corresponds to the higher range of estimates contained in several industry surveys and in other comments the Agency received. This figure represents an increase of 15 hours over our 2015 estimate of 25 hours and reflects the additional information that is required to be submitted under this final rule. We expect the hour burden will decline as responsible parties become more familiar with *ClinicalTrials.gov* and implement procedures for streamlining data collection, analysis, and formatting.

This final rule requires submission of the full protocol and SAP (if a separate document) at the time results are submitted and allows redaction by the responsible party if confidential commercial information or personally identifiable information is included. Because protocol and SAP documents already exist, we do not expect that the requirement to upload them will impose a significant burden that is not already accounted for in the results submission burden. In addition, we anticipate that the need for redaction will be very rare, so those costs should also be minimal.

Prior to this final rule, we estimated that results information would be submitted for 3,700 applicable clinical trials per year, which is the estimated number of clinical trials that would have been included in marketing applications for drug products, biological products, and device products that were initially approved, licensed, or cleared by the FDA and subject to the basic results reporting provisions of section 402(j) of the PHS Act. Under the final rule, results information is required to be submitted as specified in the final rule for all applicable clinical trials that are subject to the registration requirement and that reach their completion date after the effective date of the final rule (*i.e.*, an estimated 7,400 clinical trials per year). Applying the 40 hour figure to 7,400 applicable clinical trials per year produces a total estimated burden of 296,000 hours per year for submitting clinical trial results information. Our 2015 estimate was 92,500 hours.

We also estimated that, on average, each results record will be updated 2 times after the initial submission to reflect changes in data analysis or the submission of additional results from other pre-specified outcome measures (*e.g.,* submitting partial results). This estimate is based on user data collected to date, which indicates that each result record is updated, on average, 1.25 times after initial submission. We estimated that each such update will take 10 hours, on average. This figure is 2 hours over our 2015 estimate of 8 hours and reflects ongoing experience with data submission to *ClinicalTrials.gov.* Applying these estimates to 7,400 applicable clinical trials per year produces an estimate of 148,000 hours per year for updates to clinical trial results information (2 updates per trial), compared to 59,200 hours for the 3,700 applicable clinical trials estimated under the existing information collection. Combining the figure for updates with the estimate of the initial burden of submitting clinical trial results information, produces a total estimated annual hour burden for results information submission under the final rule of 444,000 hours, compared with 151,700 hours under the existing information collection. These estimates include the time involved in addressing any issues identified during quality control review of submitted results information.

To calculate the economic cost of clinical trial results information submission, we examined the average wages of workers in the pharmaceuticals and medical equipment industries who typically are involved in submitting clinical trial results information. Based on our experience in operating the results database and our consultations with data submitters, we believe that this task is performed generally by clinical researchers who are more experienced than those involved in registration. Based on May 2015 data from the U.S. Bureau of Labor Statistics, we identified the average hourly wage rate of $55.02, which corresponds to the mean hourly wage of a medical scientist (except epidemiologists) working in the pharmaceutical and medicine manufacturing industries. We doubled this wage rate (to $110.04) to account for benefits and overhead. Using this adjusted wage rate, we estimate a total annual cost of results information submission under this final rule, including updates, of $48,857,760 (Table 1). This represents an increase of $32,162,692 per year over our 2015 estimate of $16,693,068.

3. Delayed Submission of Results via Certification or an Extension Request

We also have estimated the average time and cost associated with the submission of certifications and extension requests to delay results information submission, consistent with § 11.44(b), (c) and (e). Responsible parties for applicable clinical trials may submit a certification to delay results information submission for an applicable clinical trial provided that initial approval, licensure, or clearance or approval, licensure, or clearance of a new use for the studied product is sought. We estimate that the number of clinical trials that will qualify for delayed submission of results in a given year will not exceed the estimated number of newly initiated applicable clinical trials per year that are conducted under an IND or IDE. Such clinical trials study drug products (including biological products) and device products that are unapproved, unlicensed, or uncleared or that are already approved, licensed, or cleared for one use but are seeking approval, licensure, or clearance of a new use. While some responsible parties might elect to submit clinical trial results information 1 year after the primary completion date instead of certifying for delayed submission, for purposes of this estimate, we assume that they all will elect to submit a certification to delay results information submission. (Note that the subsequent burden of submitting clinical trial results information is captured by the calculations in Section 2 above.) Using the same FDA data we used to estimate the number of applicable clinical trials subject to the registration requirements of this final rule, we estimate that certifications will be submitted for 5,150 trials per year. We estimate that it will take no more than 30 minutes for a responsible party to determine that an applicable clinical trial is eligible for a certification (and to verify the eligibility with a sponsor or manufacturer, if necessary) and to submit the necessary information to *ClinicalTrials.gov.* Using this figure produces an estimated annual hour burden of 2,575 hours for certifications. We estimate that the hourly wage of personnel who would submit the certification is the same as that for submitting clinical trial results information, or $55.02. Doubling this wage rate to account for benefits and overhead produces an annual estimated cost of $283,353 per year.

To estimate the number of good-cause extension requests, we considered several factors, including the rate of submission of requests between 2008 and 2015. A total of 192 requests were submitted during those 8 years (*i.e.,* 24 requests per year on average). Many of these requests were not needed in order to delay results information submission because the estimated primary completion date of the applicable clinical trial had changed. An extension request is not needed in such these situations because a responsible party need only update the estimated primary completion date to reflect changes in the progress of the trial. Other extension requests were submitted for clinical trials that were not applicable clinical trials subject to section 402(j) of the PHS Act. Under the rule, the approach outlined in § 11.22(b) and described in Section IV.B.2 of this preamble can be used to determine that the clinical trial is not an applicable clinical trial that is subject to this final rule. When these unnecessary requests are excluded, we received about 20 requests per year to delay results information submission for applicable clinical trials for which the actual primary completion date had passed. We have not attempted to estimate the number of responsible parties who may have thought they had a good cause for delaying submission but, rather than seeking the extension, chose instead to not submit results on time.

Under the final rule, we expect that the number of extension requests will increase as responsible parties gain more clarity about the deadlines for submitting clinical trial results information. We, thus, estimate that approximately 200 requests will be submitted per year, which represents a 10-fold increase over the annual rate of submissions to date. The estimated 200 requests is equivalent to 3 percent of all applicable clinical trials for which clinical trial results information is to be submitted in a given year (*i.e.,* 200 out of 7,400). It also represents about 10 percent of the applicable clinical trials that do not certify for delayed results information submission. We believe the 10-fold increase will also account for any responsible parties who will now seek an extension rather than simply not submitting results on time. While responsible parties may request an extension request even after they have filed a certification, we do not expect this to happen frequently. Moreover, as explained in Section IV.C.3 of this preamble, we expect that extensions will be granted in only a limited set of circumstances where "good cause" has been demonstrated. In cases where an extension request is denied, the responsible party will have the opportunity to appeal the denial. If we estimate that 50 percent of extension requests are denied and that 50 percent of denials result in an appeal, we expect to receive 50 appeals per year.

We estimate that the time required for gathering the information for a good-cause extension request or appeal and submitting it to *ClinicalTrials.gov* will be no more than 2 hours. Using this figure, we estimate that the annualized hourly burden for extension requests and appeals will be 500 hours. We expect that requests will be submitted by individuals familiar with the results information submission requirements and, therefore, use an hourly wage of $55.02. Doubling this wage rate (to $110.04) to account for benefits and overhead brings the annualized cost of extension requests to $55,020. Combining the estimated costs for certification and extension requests produces a total cost of $338,373 per year (Table 1). Prior to the rule, we estimated that 3,700 certifications would be submitted by responsible parties seeking initial approval, licensure, or clearance or approval, licensure, or clearance of a new use of a drug product (including biological product) or device product studied in an applicable clinical trial and that 200 extension requests would be submitted per year. These figures yield an estimated annual cost of $245,114 meaning that the incremental cost attributable to this rule is $93,259 per year.

We note that under § 11.54, responsible parties may also seek a waiver from any applicable requirement of the rule. Such waivers are available only under extraordinary circumstances that must be consistent with the protection of the public health or in the interest of national security. We expect the need for such waivers to be exceedingly rare. As such, we are subsuming the costs of waiver requests in the extension request estimates.

4. Triggered Submission of Clinical Trial Information Following a Voluntary Submission

Section 11.60 of the final rule implements section 402(j)(4)(A) of the PHS Act and stipulates that if a responsible party voluntarily registers or submits results information for a clinical trial of an FDA-regulated drug product or device product that is not an applicable clinical trial subject to the mandatory clinical trial information submission requirements, that responsible party must, under specified circumstances, also submit information for other applicable clinical trials that are included in a marketing application or premarket notification that is submitted to FDA and for which clinical trial information has not already been submitted to *ClinicalTrials.gov.* The types of trials for which the voluntary submission of clinical trial information would invoke this requirement include, *e.g.,* phase 1 trials of drug products, small feasibility studies of device products (neither of which is considered to be applicable clinical trial) or applicable clinical trials that are not otherwise subject to section 402(j) of the PHS Act because they were initiated prior to the date of enactment of FDAAA and were no longer ongoing as of December 26, 2007. The voluntary submission of clinical trial information for such trials will trigger a requirement to submit clinical trial information for other applicable clinical trials that are included in the marketing application for a drug product or device product only if the entity submitting the marketing application or premarket notification is the same as the responsible party for those other trials and still has access to and control over the necessary data.

In practice, we expect that the requirement under section 402(j)(4)(A) of the PHS Act to submit clinical trial information for applicable clinical trials not otherwise registered in *ClinicalTrials.gov* will be triggered infrequently. In most cases, when clinical trial information is submitted voluntarily, we expect that the applicable clinical trials required to be submitted in a marketing application that includes the voluntarily-submitted clinical trial would be registered in *ClinicalTrials.gov* consistent with section 402(j)(2)(C) of the PHS Act and § 11.60. For example, the voluntary submission of information for a phase 1 trial of an unapproved drug product would trigger the submission of information for an applicable clinical trial that was not previously submitted only if the responsible party for the voluntarily-submitted trial is the same as the entity submitting the marketing application, the applicable clinical trial is required to be submitted in that marketing application, and the marketing application is for the same use studied in the voluntarily submitted trial. For purposes of this analysis, we estimate that 1 percent of the clinical trials registered voluntarily with *ClinicalTrials.gov* each year could trigger the submission of clinical trial information for an applicable clinical trial for which clinical trial information was not otherwise required to be submitted to *ClinicalTrials.gov.* Of the 19,170 clinical trials that are registered every year, on average, with *ClinicalTrials.gov,* we estimate that 11,770 are voluntary or do not fall under the rule (*i.e.* non-regulated) submissions (all but the 7,400 that are applicable clinical trials). Using 1 percent estimate and this figure, we calculate that voluntary registrations will trigger the required submission of clinical trials information for an estimated 118 clinical trials per year. Based on our experience to date with voluntary submissions, we expect that for at least three-quarters of those triggered trials (88 total) registration information only will need to be submitted; for the other quarter, results information will need to be submitted. For those clinical trials for which only registration information is required, we estimate that it will take a data submitter with an average hourly wage rate of $36.02 (consistent with the figures used for registration of applicable clinical trials) 8 hours to register the clinical trial. Doubling the wage rate to account for benefits and overhead produces an estimated cost of $50,716 per year. Submitted information will not generally need to be updated because the clinical trial will, in general, have reached its primary completion date by the time the requirement to submit clinical trial information is triggered. For the remaining quarter of the triggered clinical trials (30 total), we estimate that the hourly burden would equal the 40 hours estimated for results information submission for other applicable clinical trials plus 5 hours to account for the additional data elements that are specified in § 11.60(b)(2)(i)(B) and (c)(2)(i)(B). Using these figures and doubling the estimated average hourly rate of $55.02, we estimate the annual cost of submission as $148,554. Combining this figure with the $50,716 figure for triggered clinical trials that submit only registration information produces a total annual estimated cost of $199,270 for the submission of clinical trial information triggered by the voluntary submission of information under § 11.60 (Table 1). Because the submission of clinical trial information triggered by the voluntary submission of information was not required prior to the rule, the incremental cost attributable to this rule will be the full estimated cost of $199,270 per year. We note that each year a number of studies will likely be registered in *ClinicalTrials.gov* that are not subject to section 402(j) of the PHS Act.

Investigators may choose to register such studies in order to assist in the recruitment of subjects or to follow other policies, *e.g.,* scientific journal publication requirements, or for other reasons. Examples of such studies include studies of surgical or behavioral interventions. It is also possible that investigators may choose to register studies and report results information for clinical trials not subject to section 402(j) of the PHS Act because the final rule may bring about greater awareness of the registration or results information submission process.

Because we are not able to distinguish the portion of voluntary submissions of information to the database attributed to increased awareness of the final rule, the cost to entities that submit clinical trial information, but are not required to do so under section 402(j) of the PHS Act, as implemented by this final rule, are not included in this cost estimate. We do, however, account for them in the discussion of the PRA clearance of the requirements under this rule because we expect submissions to increase as a result of some combination of this rule and the contemporaneous NIH policy document, both of which are associated with the same OMB control number.

5. Expanded Access Records

As specified in § 11.28(a), if an expanded access record is available for an investigational drug product (including a biological product) that is studied in an applicable drug clinical trial, the responsible party for that applicable clinical trial must, if it is both the manufacturer of the investigational product and the sponsor of the applicable clinical trial, include the NCT number of the expanded access record with the clinical trial information submitted at the time of registration. If an expanded access record for the investigational drug product (including a biological product) being studied in the applicable clinical trial has not yet been submitted to *ClinicalTrials.gov,* and if the responsible party is both the manufacturer of the investigational product and the sponsor of the applicable clinical trial, the responsible party must create an expanded access record by submitting data elements in § 11.28(c). To determine the cost and burden associated with the creation of this record, we relied on information from FDA. Each year, an estimated 135 investigational drug products (including biological products) that were not previously available for expanded access use will be made available for individual patient expanded access (including emergency use) by responsible parties who are required to create an expanded access record. FDA estimates that 10 treatment INDs or treatment protocols are initiated annually and that expanded access use for intermediate size patient populations is initiated 68 times annually. These are the three types of expanded access for which information in § 11.28(c) must be submitted to *ClinicalTrials.gov* under this final rule for an expanded access record. We estimate the time required to submit the required information for an expanded access record to be 2 hours, which is one-quarter of the estimated time to register an applicable clinical trial. Compared to the number of data elements required under the rule for applicable clinical trials, only about half as many data elements are required for an expanded access record for expanded access use under treatment INDs, treatment protocols and for intermediate-size patient populations, and still fewer for expanded access records for individual patient expanded access use. The rule also does not require some of the more detailed data elements, such as Primary Outcome Measure, Secondary Outcome Measure, Individual Site Status, and Facility Location information. We also estimate an average of 2 updates per expanded access record per year, each taking which 15 minutes. We estimate the total hour burden associated with 213 expanded access records (*i.e.,* 135 investigational drug products available for single patient access, 68 for intermediate size patient populations and 10 treatment INDs or treatment protocols) to be 533 hours per year (426 hours for initial information submission plus 107 hours for information updates). We expect that expanded access records are submitted by staff with the same qualifications as those registering applicable clinical trials and, hence use an estimated hourly wage of $36.02. Doubling this wage rate to $72.04 to account for benefits and overhead results in a total estimated annual cost of $38,361 (Table 1). Because the submission of expanded access records was not included prior to rulemaking, the incremental cost attributable to this rule is the full estimated cost of $38,361 per year.

6. Institutional Compliance Costs

Organizations such as academic institutions may decide to devote more resources to ensure that applicable clinical trials being conducted in their organizations are compliant with the final rule. They may elect to do so in order to avoid the consequences of non-compliance, which, for an organization receiving federal funding for the clinical trial, could include suspension of grant funding were there to be a finding of non-compliance. These additional resources would primarily involve additional staff support to help facilitate and monitor compliance on the part of responsible parties within the organization.

Institutions of higher education that receive federal funding generally cover compliance activities under indirect costs rates that are negotiated for each institution. Although the final rule may cause an increase in compliance costs, the increase is anticipated to be incremental. Institutions can obtain up to 26 percent of their administrative costs to pay for administrative support.

To estimate the costs that institutions may bear because of the final rule, we estimated the current compliance costs (FDAAA pre-rule). We first identified the number of industry and non-industry sponsors of probable applicable clinical trials (pACTs) who submitted results to *ClinicalTrials.gov* in 2015 and separated them into three categories based on volume of pACTs submitted per year. The categories were low volume, defined as 1 to 5 pACTs per year; medium volume, defined as 6 to 10 pACTs per year; and high volume, defined as 11 or more pACTs per year. We identified 363 non-industry sponsors (312 low volume, 29 medium volume, 22 high volume) and 277 industry sponsors (238 low volume, 17 medium volume, 22 high volume) who submitted pACT results information in 2015. We then multiplied the current number of full time employees (FTEs) per organization, a figure estimated to be 0.5 FTEs [Ref. 117], by the total number of industry and non-industry sponsors who submitted pACT results information in 2015. We then multiplied the estimated total FTEs by the estimated annual salary costs, using U.S. Bureau of Labor Statistics data on average wages from May 2015 of medical scientists (except epidemiologists) in the pharmaceuticals and medicine manufacturing ($36.02 per hour) and medical scientists (except epidemiologist) in a college, university or professional school ($32.17 per hour). We doubled these wage figures (to $72.04 and $64.34) to account for benefits and overhead. The final total product of the FDAAA pre-rule institutional yearly cost of compliance for all sponsors was estimated to be $45 million (Table 1).

We next estimated the cost of the final rule and used reported number of compliance staff from a high volume sponsor [Ref. 118]. We assumed that the required number of FTEs will depend on the number of trials to be overseen and thus estimated that low volume sponsors will need 0.5 FTEs. We assumed that, in most cases, low volume sponsors will not need to hire additional FTEs because reporting responsibilities will be fulfilled by the responsible parties themselves (as detailed and calculated in Sections 1–3 above). We also estimated that medium volume sponsors will need 2 FTEs and high volume sponsors will require an estimated 3 FTEs. We calculated the product of the total institutional cost with the adjusted increase in compliance staff is estimated to be $70.3 million (Table 1). The difference between the cost estimate of the final rule and the estimate of the amount spent currently on compliance (FDAAA pre-rule) is $25.2 million. We believe these estimates are likely to be overestimates because FTEs involved in FDAAA final rule compliance activities at many institutions will be engaged in other compliance activities that relate to other federal and state laws and regulations governing clinical research (*e.g.,* FDA IND/IDE and IRB regulations, Common Rule) as well as compliance activities due to non-governmental clinical trial-related policies (*e.g.,* journal editors require trial registration before the first participant is enrolled as a condition for the publication results after study completion) [Ref. 98]. We also assumed that the FTEs will spend some time up front engaged in developing programs or systems to facilitate institutional compliance efforts, and that they will later shift their focus to compliance monitoring activities. Therefore, the number of attributable FTEs is constant over time and the cost of updating existing IT programs/systems is already included. We also did not differentiate between industry and non-industry organizations to reflect the fact that industry organizations have well-established regulatory affairs operations, the functions of which include compliance monitoring and oversight. We believe that many of these operations are already engaged in oversight activities to support compliance with the statutory requirements. Thus, the costs for industry organizations are likely an overestimate.

We estimate the annualized cost to the Federal Government due to the final rule data collection requirements is approximately $1.4 million for *ClinicalTrials.gov* activities. This figure includes the increased cost associated with contractors required to develop software and operate the database and senior scientists, analysts, and other staff needed to carry out and oversee *ClinicalTrials.gov* operations as well as other costs including database equipment and maintenance.

We estimate the total annual cost of the final rule to be $59.6 million. We expect that over time the cost of complying with the final rule will decline notably as responsible parties become more familiar with the registration and results information submission requirements as well as the data submission and review processes. Many institutions may have already developed systems and procedures to support investigators in fulfilling their reporting responsibilities under the statute. Also, a number of clinical trial data management software tools currently allow users to output registration information for automatic uploading of files in bulk to *ClinicalTrials.gov.* We expect that by clarifying the requirements for submission of clinical trial in this final rule, responsible parties will automate portions of the data extraction and formatting processes for required results information, significantly reducing the burden and associated cost of compliance with this final rule.

TABLE 1—ESTIMATED ANNUAL COST OF FINAL RULE

Provision	Final rule section(s)	Estimated annual cost prior to rulemaking	Estimated annual cost under the final rule	Incremental cost above pre-rule data collection
Registration of applicable clinical trials, including updates	11.28(a),(b), 11.64(a).	$12,261,208	$12,794,304	$533,096
Results information submission for applicable clinical trials, including updates.	11.48, 11.64(a).	16,693,068	48,857,760	32,162,692
Submission of certifications, extension requests, and appeals to delay results information submission.	11.44(b), (c), (e).	245,114	338,373	93,259
Triggered registration and results information submission following voluntary submissions.	11.60	0	199,270	199,270
Submission of expanded access records	11.28(c)	0	38,361	38,361
Institutional compliance costs		45,042,920	70,287,277	25,244,357
Cost to the Federal Government		4,826,307	6,190,784	1,364,477
Total	N/A	79,068,617	138,706,129	59,635,512

F. Alternatives to the Final Rule

Section 402(j)(3)(D)(v)(VI) of the PHS Act requires the Secretary to promulgate regulations to expand the registry and results data bank and to address specific issues that are enumerated in the statute. Section 402(j)(2)(A)(iii) of the PHS Act also authorizes the Secretary to make additions or modifications to the statutorily enumerated requirements for registration of applicable clinical trials. This final rule implements and expands the basic provisions mandated by section 402(j) of the PHS Act that became effective prior to rulemaking on the schedule established by the statute. In the NPRM, we described various alternatives that we considered in exercising authority to add or modify the statutory provisions and in addressing the topics that were required to be addressed through rulemaking. In developing the final rule, and informed by public comments, we considered alternatives approaches that could be taken in the final rule. We discuss two here.

One important provision of the final rule requires results information from applicable clinical trials of unapproved, unlicensed, or uncleared products to be submitted. The Agency has concluded that the public health benefits of this approach, as discussed in above in Section D, justify the costs. In particular, trials of products that are unapproved, unlicensed, or uncleared are unlikely to be published if the results of these trials would not help support applications for product approval, licensure, or clearance. This rule's requirements that responsible parties submit results information from applicable clinical trials of unapproved, unlicensed, or uncleared products regardless of whether approval, licensure, or clearance is sought, as well as the public posting of this information, are expected to help address bias in the literature and selective publication of results. The requirement for results information submission will make information public that otherwise likely would not have reached the public domain. The availability of results information from such applicable clinical trials will help to prevent the evidence base, which serves as a foundation for future research, systematic reviews, and clinical practice guidelines, from being skewed. The alternative position—not requiring results information submission for applicable clinical trials of unapproved, unlicensed, or uncleared products—would decrease the costs of the rule as estimated in Section V.E.2, but it would likely be costly to public health because of the absence of the benefits described in Section V.D. Therefore, the Agency believes that the benefits to public health justify the cost of compliance.

The final rule also requires submission of the final research protocol and SAP as part of the results information (discussed in Section III.D of the preamble). We expect the protocol to provide users of *ClinicalTrials.gov* with more complete information about the trial. One of the aims of section 402(j) of the PHS Act and of the rule is to "provide more complete results information." We believe this goal complements the goals of increased transparency and accountability. As such, the submission of the protocol and SAP will provide more complete results information and significantly enhance the understanding of the trial and the context of the data fields provided. Because protocol and SAP documents already exist, we do not expect that the requirement to upload them will impose a significant burden that is not already accounted for in the results submission burden. The alternative—not requiring the submission of protocol—would have little to no effect in reducing the burden of the rule, but it would decrease public health benefits by decreasing the transparency of clinical trial results information.

G. Regulatory Flexibility Act

The RFA (5 U.S.C. 601–612) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule will affect a number of small entities that conduct clinical trials of drug products and device products, but the Agency estimates that the costs incurred by small entities would be limited, especially in relation to the other costs associated with conducting a clinical trial. As explained below, the Agency believes that the final rule is not likely to have a significant economic impact on a substantial number of small entities.

The companies that would be affected by this final rule are classified in seven separate 2012 North American Industrial Classification System (NAICS) categories by the Census Bureau. The affected industries are NAICS 325412—Pharmaceutical Preparation; NAICS 325414—Biological Products (except diagnostic); NAICS 334510—Electromedical and Electrotherapeutic Apparatus; NAICS 339112—Surgical and Medical Instrument; NAICS 339113—Surgical Appliance and Supplies; NAICS 339114—Dental Equipment and Supplies; NAICS 339115—Ophthalmic Goods [Ref. 119]. The Small Business Administration (SBA) size standards define small entities as those companies with a maximum number of employees. The 2016 size standards for all these industries are shown in the table below [Ref. 120]. The most recent data from the U.S. Census of Manufacturers that offers the level of detail for establishments at or near the employee size limits as defined by SBA is from 2012 [Ref. 121]. In each of these establishment size categories, large majorities (*i.e.,* 90 percent or more) of the establishments meet the criteria as small entities [Ref. 122]. Even taking into account that many of these establishments are parts of multi-establishment corporations, significant numbers of companies would still qualify as small entities and have fewer than 100 employees across all of these categories (*i.e.,* ranging from 79 percent to 96 percent of all establishments within a category). Although the Agency expects that most companies sponsoring applicable clinical trials would be larger than the average-sized company in their industry, the Agency concludes that a substantial number of companies would still qualify as small entities.

TABLE 2—SIZE STANDARDS FOR AFFECTED COMPANIES

NAICS code and industry description	Size standards in number of employees
NAICS 339113—Surgical Appliance and Supplies	750
NAICS 339114—Dental Equipment and Supplies	750
NAICS 339112—Surgical and Medical Instrument	1,000
NAICS 339115—Ophthalmic Goods	1,000
NAICS 325412—Pharmaceutical Preparation	1,250
NAICS 325414—Biological Products (except diagnostic)	1,250
NAICS 334510—Electromedical and Electrotherapeutic Apparatus	1,250

The cost analysis presented above indicates an estimated cost of compliance with this final rule of $17,907 per applicable clinical trial ($132,515,345 for 7,400 clinical trials per year). While some larger firms could be the responsible party for multiple applicable clinical trials in the same year, we expect most small firms would be responsible for no more than one applicable clinical trial per year. Using data from the 2012 Census of Manufacturers, we used the average value of shipments for establishments in these industries to calculate the cost percentage of the rule on small entities. Assuming that small operations with one to four employees had one applicable clinical trial that was required to submit registration or results information each year, the costs of this final rule would representan estimated 3.4 percent of the annual value of shipments. For establishments with 50 to 99 employees, the costs of this final rule would represent an estimated 0.9 percent of the value of shipments, even if they were responsible for 10 applicable clinical trials administered annually. For establishments with 100 or more employees, the costs of this final rule would represent an estimated 0.1 percent of the value of shipments even with 10 applicable clinical trials administered annually. Although the figure for establishments with one to four employees in one industry was estimated to be 3.4 percent at most, the remaining figures are well below the threshold of 3 to 5 percent of the total revenue for small entities needed to consider that this final rule would have a significant economic impact on a substantial number of small entities. The Agency concludes and certifies that this final rule would not have a significant economic impact on a substantial number of small entities.

In practice, we expect the burden on small firms will be significantly lower than this estimate. In general, the applicable clinical trials initiated by small firms will be less complex than the applicable clinical trials initiated by large firms, including, for example, fewer trial locations (sites), shorter duration, and fewer outcome measures. As a result, the amount of results information to be submitted—and the time and cost associated with such submissions—will be less than for larger entities and represent a smaller share of shipments. In addition, these costs would affect only a fraction of small firms in any given year. For example, by our estimates, registration information would be required to be submitted (and results information subsequently submitted) for approximately 500 applicable device clinical trials in any given year. Information from the 2012 Economic Census of the United States indicates that there are approximately 11,500 companies in the U.S. that are involved in the manufacture of medical devices and that almost 11,000 of them have fewer than 100 employees. Even if no company engaged in more than one applicable clinical trial at the same time, then on average, less than 10 percent of all device manufacturers would initiate a trial subject to the registration and results information submission requirements of this final rule in any given year (700 applicable device clinical trials per year divided by 11,500 firms equals 0.061 or 6.1 percent).

H. Unfunded Mandates Reform Act of 1995

Section 1352(a) of the Unfunded Mandates Reform Act of 1995 requires that the Agency prepare, among other things, a written statement that includes an assessment of anticipated costs and benefits before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year" (2 U.S.C. 1532(a)). The current threshold, adjusted for inflation using the 2015 Implicit Price Deflator for the Gross Domestic Product, is $146 million. We do not expect the direct burden of this final rule, including the cost of compiling, submitting, and updating clinical trial registration and results information for applicable clinical trials, to result in any 1 year expenditure that would meet or exceed this amount. Nor do we expect that State or local governments would bear a significant fraction of this cost, as most of the entities affected by the final regulation would be private entities. As a result, we conclude that this rule has no consequential effect on State, local, or tribal governments or on the private sector. We have determined that this final rule would not constitute a significant rule under the Unfunded Mandates Reform Act of 1995 because it would impose no mandates with costs exceeding the current threshold.

I. Federalism

Executive Order 13132, Federalism, establishes certain requirements that an Agency must meet when it promulgates a proposed rule (and subsequent final rule) "that imposes substantial direct compliance costs on State and local governments," preempts State law, or otherwise has federalism implications. The Agency has analyzed this final rule in accordance with the principles set forth in Executive Order 13132 and has determined that this final rule does not contain policies that would impose any "substantial direct compliance costs on State or local governments[.]" This final rule, does, however, have federalism implications.

Section 801(d)(1) of FDAAA expressly provides a preemption provision as follows: "Upon the expansion of the registry and results data bank under section 402(j)(3)(D) of the Public Health Service Act . . . no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database." We interpret this language to prohibit a State or political subdivision of a State from establishing any requirement for the inclusion of information in a database that is (1) clinical trial registration information, as that term is defined in § 11.10, *i.e.*, the actual registration data elements; (2) clinical trial results information required to be submitted under section 402(j)(3) of the PHS Act and this part; or, (3) information that is otherwise collected through any data element in ClinicalTrials.gov, such as information relating to voluntary submissions and other information whether or not required to be submitted under section 402(j) of the PHS Act and this part. We do not interpret section 801(d)(1) of FDAAA to preempt other types of reporting and/or data collection that States may require related to public health, disease surveillance, clinical care, or the practice of medicine such as patient and disease registries or public health surveillance registries.

VI. Paperwork Reduction Act of 1995

This final rule contains requirements that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). Sections 11.28, 11.48, 11.60, 11.62, and 11.64 of this rule contain information collection requirements that are subject to OMB approval. A revision of the 2015 PRA clearance for clinical trial registration and results information submission (OMB 0925–0586) to meet the requirements of this final rule will be submitted to OMB for review. It will also be updated to request approval to collect clinical trial registration and results information under a final policy that NIH is issuing in tandem with the final rule that will apply to all NIH-funded clinical trials, including those not subject to the rule [Ref. 65].

Section VII of the NPRM, the Agency provided an estimate of the annualized burden hours associated with the information collection requirements included in the proposed rule, and we invited comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NIH, including whether the information will have practical utility; (2) the accuracy of the estimate of the burden of the proposed collection of information by NIH, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology (79 FR 69663). The comments we received are discussed in Section V.A of the final rule.

A description of the information collection requirements included in this rule is provided in the Regulatory

Impact Statement (Section V of this preamble) and is summarized in this section of the preamble with an estimate of the annualized burden hours. Included in this estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing, reviewing, updating, and correcting each collection of information.

Organizations and individuals desiring to submit comments on the information collection and submission requirements should send their comments by October 21, 2016 to (1) Ms. Mikia Currie, Project Clearance Officer, National Institutes of Health, Rockledge Centre 1, 6705 Rockledge Drive, Room 3509, Bethesda, Maryland 20817, telephone 301–594–7949 (not a toll-free number); and (2) the Office of Information and Regulatory Affairs, OMB, *OIRA_submission@omb.eop.gov,* or by fax to 202–395–6974, and mark "Attention: Desk Officer for the National Institutes of Health, Department of Health and Human Services." After we obtain OMB approval, we will publish the OMB control number in the FR.

The estimate includes the annual hourly burden for submission, updating, and correction of information both for applicable clinical trials that are subject to this rule and for the larger number of clinical trials for which information is submitted to *ClinicalTrials.gov* on a voluntary basis in order to recruit subjects, remain eligible to publish summary articles in scientific journals that follow the guidelines of the ICMJE, to comply with NIH or other public, company, or other organizational policies regarding public disclosure of clinical trial information, or for other purposes.

The burden for trials that are subject to this rule follows the estimates presented in Section V of this preamble. For registration, we estimated 7,400 applicable clinical trials which included the number of clinical trials that would be subject to mandatory registration under the rule. This estimate reflects the number of protocols for applicable clinical trials that are submitted to FDA under an IND or IDE (*i.e.,* 5,150), as well as applicable clinical trials that are not conducted under an IND or IDE (*i.e.,* 2,250). We also increased the estimated hour burden of registration from 7 hours in the 2015 information collection, to 8 hours to reflect the additional data elements that would be required under this rule. For results information submission, we have increased from 3,700 to 7,400 our estimate of the number of applicable clinical trials that would be subject to mandatory results information submission under this rule. The final rule requires the submission of results information for all registered applicable clinical trials, regardless of whether or not the drug product (including biological product) or device product under study in the trial is approved, licensed, or cleared. We have made corresponding increases in the estimated number of applicable clinical trials for which a certification to delay results information submission would be submitted. We have also increased the estimated hour burden for submitting results information from 25 hours to 40 hours to account for the additional results information that would be required to be submitted under this rule. In addition, we have added estimates of the burden associated with the submission of registration and results information that could be triggered by some voluntary submissions of clinical trial information under § 11.60. Finally, we have included a separate estimate of the burden associated with the creation of an expanded access record if an investigational drug product (including a biological product) that is studied in an applicable clinical trial is available under expanded access. See figures in Table 3.

As we noted in Section V, a number of trials studies will likely be registered in *ClinicalTrials.gov* that are not subject to section 402(j) of the PHS Act. Investigators may choose to register such studies in order to assist in the recruitment of subjects or to comply with medical journal policies that make registration in a publicly accessible repository a condition of publication. In addition, starting in 2017, clinical trial registration and results information will also be collected from NIH-funded investigators whether or not they are subject to the final rule, which will lead to an increase in the number of non-regulated submissions.

In order to estimate the impact of the NIH policy, over and above the impact of the rule, we began by determining that 526 NIH funded trials that are likely not applicable clinical trials were first registered in 2015. These represent the likely number of trials that will have the additional burden of submitting results per year under the NIH policy. In addition, we estimated that approximately 25 percent of NIH-funded trials that are not applicable clinical trials have not been registered in the past (despite encouragement from NIH and the journal editors' policy). This leads to an estimate of an additional 131 trials registered and reporting results per year. The total number of non-applicable clinical trials that will register and submit results due to the NIH policy is estimated to be 657 per year. Investigators subject to the NIH policy will be expected to submit the same information within the same timeframes as parties subject to 402(j)(2)(C) of the PHS Act. We, thus, use the assumptions here that we used to estimate the burden for applicable clinical trials, *i.e.,* initial submission of registration information will take an average of 8 hours, updates of 2 hours apiece will take place 8 times during the course of the study and, initial results submission will take on average 40 hours with 2 expected updates requiring an average of 10 hours total. Adding the registration burden to the results information burden yields an estimated total annual hour burden of 55,188 (Table 3).

In order to estimate the burden for clinical trials that are not subject to section 402(j) of the PHS Act, including the requirements in this final rule, and will not be subject to the NIH policy, we examined registrations to *ClinicalTrials.gov* in calendar year 2015 and found that a total of 19,170 clinical trials were registered that year. Since we estimate that 7,400 of these are applicable clinical trials, the remainder 11,770 trials, can be considered voluntary or to not fall under the rule. Of these, 526 were NIH funded. This leaves an estimated 11,244 trials registered per year that do not fall under either the rule or the NIH policy.

We expect that these clinical trials will submit the same clinical trial registration information as is submitted for applicable clinical trials that are subject to the rule. We expect that information submitted for such clinical trials will be updated as frequently as information for applicable clinical trials that are subject to the rule. Therefore, for calculating the registration burden associated with these clinical trials, we use the same assumptions as for applicable clinical trials required to register under section 402(j)(2)(C) of the PHS Act, *i.e.,* initial submission of registration information will take an average of 8 hours, updates of 2 hours apiece will take place 8 times during the course of the study. Applying these figures yields an estimated annual burden of 269,856 hours, of which 89,952 derives from the initial registration and 179,904 derives from updates (Table 3).

For clinical trials that are not subject to section 402(j) of the PHS Act, including the requirements in this final rule, or the NIH policy, we expect that often only clinical trial registration information, and not both registration and results information, will be submitted. To estimate the number results submissions will be submitted, we looked at results submissions in 2015 and found that 1,580 were for clinical trials that were neither applicable clinical trials nor funded by NIH. We estimate that this number will grow slightly, secondary to various other funder policies (*e.g.*, PCORI). We, therefore, estimate that we will receive approximately 2,000 results per year that are not due to either the rule or the NIH policy. We estimate that the time required to submit clinical trial results information for such clinical trials would be equivalent to that for applicable clinical trials required to register under section 402(j)(2)(C) of the PHS Act. Using those figures, we estimate that the total annual hour burden for submitting clinical trial results information for clinical trials that are not otherwise required to submit results information would be 80,000 hours, plus 40,000 hours for updates (Table 3).

TABLE 3—ESTIMATED BURDEN FOR REGISTRATION AND RESULTS INFORMATION SUBMISSION AT CLINICALTRIALS.GOV

Type of respondents	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Regulated Submissions (Subject to this Rule)				
Registration	7,400	1 Initial	8	59,200
		8 Subsequent Updates	2	118,400
Results Information	7,400	1 Initial	40	296,000
		2 Subsequent Updates	10	148,000
Certifications to delay results submission	5,150	1	0.5	2,575
Extension requests and appeals	250	1	2	500
Registration triggered by voluntary submission.	88	1	8	704
Results triggered by voluntary submission	30	1	45	1,350
Expanded access records	213	1 initial	2	426
		2 Subsequent Updates	0.25	107
Subtotal for Regulated Submissions	627,262			
Non-regulated Submissions Related to the NIH Policy				
Registration	657	1 Initial	8	5,256
		8 Subsequent Updates	2	10,512
Results information	657	1 Initial	40	26,280
		2 Subsequent Updates	10	13,140
Subtotal for Non-regulated Submissions Related to the NIH Policy.	55,188			
Non-regulated Submissions				
Registration	11,244	1 Initial	8	89,952
		8 Subsequent Updates	2	179,904
Results information	2,000	1 Initial	40	80,000
		2 Subsequent Updates	10	40,000
Subtotal for Non-regulated Submissions	389,856			
Subtotal for Non-regulated Submissions and Submissions Related to the NIH Policy.	445,044			
Total	1,072,306			

VII. Legal Authority

These regulations are issued under the authorities contained in 42 U.S.C. 282(i); 42 U.S.C. 282(j); 5 U.S.C. 301; 42 U.S.C. 286(a); 42 U.S.C. 241(a); 42 U.S.C. 216(b); and sections 801(c)–(d), Public Law 110–85, 121 Stat. 921–922 (42 U.S.C. 282 (note)).

VIII. References

1. International Committee of Medical Journal Editors. Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals [Internet]. 2015 Dec [cited 2016 Sept 8]. Available from: *http://www.icmje.org/icmje-recommendations.pdf.*
2. ICMJE [Internet]. International Committee of Medical Journal Editors; 2016. Clinical trial registration; 2011 [cited 2016 Aug 5]; [about 2 screens]. Available from: *http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html.*
3. International Federation of Pharmaceutical Manufacturers and Associations. Joint Position on the Disclosure of Sensitive Information via Clinical Trial Registries [Internet]. 2005 Sept 5 [updated 2009 Nov 10; cited 2016 Aug 5]. Available from: *http://www.efpia.eu/uploads/Modules/Documents/november_10_2009_updated_joint_position_on_the_disclosure_of_clinical_trial_information_via_clinical_trial_registries_and_databases.pdf.*
4. Steinbrook R. Registration of clinical trials—voluntary or mandatory? N Engl J Med. 2004 Oct 28;351(18):1820–2.
5. Evans T, Gülmezoglu M, Pang T. Registering clinical trials: an essential role for WHO. Lancet. 2004 May 1;363(9419):1413–4.
6. Dickersin K, Davis BR, Dixon DO, George SL, Hawkinse BS, Lachin J, Peduzzi P, Pocock S; Society for Clinical Trials. The Society for Clinical Trials supports United States legislation mandating trials

registration. Clinical Trials. 2004;1(5):417–20.

7. Scherer RW, Langenberg P, von Elm E. Full publication of results initially presented in abstracts. Cochrane Database of Systematic Reviews. 2007 Apr 18;(2):MR000005.
8. Faubel S, Chawla LS, Chertow GM, Goldstein SL, Jaber BL, Liu KD; Acute Kidney Injury Advisory Group of the American Society of Nephrology. Ongoing clinical trials in AKI. CJASN. 2012 May 7;7(5):861–73.
9. Bourgeois FT, Murthy S, Pinto C, Olson KL, Ioannidis JP, Mandl KD. Pediatric versus adult drug trials for conditions with high pediatric disease burden. Pediatrics. 2012 Aug;130(2):285–92.
10. Li J, Lu Z. Systematic identification of pharmacogenomics information from clinical trials. Journal Biomed Inform. 2012 Oct;45(5):870–8.
11. Califf RM, Zarin DA, Kramer JM, Sherman RE, Aberle LH, Tasneem A. Characteristics of clinical trials registered in ClinicalTrials.gov, 2007–2010. JAMA. 2012 May 2;307(17):1838–47.
12. Mayor S. Half of drug trials with results on ClinicalTrials.gov are not published in journals. BMJ. 2013 Dec;347:f7219.
13. Hartung DM, Zarin DA, Guise JM, McDonagh M, Paynter R, Helfand M. Reporting discrepancies between the ClinicalTrials.gov results database and peer-reviewed publications. Ann Intern Med. 2014 Apr 1;160(7):477–83.
14. Gopal AD, Desai NR, Tse T, Ross JS. Reporting of noninferiority trials in ClinicalTrials.gov and corresponding publications. JAMA. 2015 Mar 17;313(11):1163–5.
15. Cepeda MS, Lobanov V, Berlin JA. Use of ClinicalTrials.gov to estimate condition-specific nocebo effects and other factors affecting outcomes of analgesic trials. J Pain. 2013 Apr;14(4):405–11.
16. Eguale T, Buckeridge DL, Verma A, Winslade NE., Benedetti A, Hanley JA, Tamblyn R. Association of off-label drug use and adverse drug events in an adult population. JAMA Intern Med. 2016 Jan;176(1):55–63;
17. Good CB, Gellad WF. Off-label drug use and adverse events, turning up the heat on off-label prescribing. JAMA Intern Med. 2016 Jan;176(1):63–4.
18. McCray AT. Better access to information about clinical trials. Ann Intern Med. 2000 Oct 17;133(8):609–14.
19. Ide NC, Loane RF, Demner-Fushman D. Essie: A concept-based search engine for structured biomedical text. J Am Med Inform Assoc. 2007;14(3):253–63.
20. Zarin DA, Ide NC, Tse T, Harlan WR, West JC, Lindberg DA. Issues in the registration of clinical trials. JAMA. 2007;297(19):2112–20.
21. Le Noury J, Nardo JM, Healy D, Jureidini J, Raven M, Tufanaru C, Abi-Jaoude E. Restoring Study 329: efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence. BMJ. 2015 Sep 16;351:h4320.
22. Fu R, Selph S, McDonagh M, Peterson K, Tiwari, A, Chou R, Helfand M. Effectiveness and harms of recombinant human bone morphogenetic protein-2 in spine fusion: a systematic review and meta-analysis. Ann Intern Med. 2013 Jun 18;158(12):890–902.
23. Zarin DA, Tse T. Unambiguous identification of obesity trials. N Engl J Med. 2013 Feb 7; 368(6):580–1.
24. Zarin DA, Tse T. Sharing individual participant data (IPD) within the context of the trial reporting system (TRS). PLoS Med. 2016 Jan 19;13(1):e1001946.
25. Levin LA, Palmer JG. Institutional review boards should require clinical trial registration. Arch Intern Med. 2007 Aug 13–27;167(15):1576–80.
26. Zaccara G, Perucca P, Loiacono G, Giovannelli F, Verrotti A. The adverse event profile of lacosamide: a systematic review and meta-analysis of randomized controlled trials. Epilepsia. 2013 Jan;54(1):66–74.
27. Higgins JP, Green S. Cochrane Handbook for Systematic Reviews of Interventions (version 5.1.0). 2011 Mar [cited 2016 Aug 23]. Available from: *http://handbook.cochrane.org.*
28. Presidential Commission for the Study of Bioethical Issues. Moral Science: Protecting Participants in Human Subjects Research [Internet]. [updated 2011 Dec; cited 2016 Aug 5]. Available from: *http://bioethics.gov/node/558.*
29. Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary. Washington (DC): National Academies Press (US); 2010. Available from: *http://www.ncbi.nlm.nih.gov/books/NBK50892/.*
30. Dear RF, Barratt AL, McGeechan K, Askie L, Simes J, Tattersall MH. Landscape of cancer clinical trials in Australia: using trial registries to guide future research. Med J Aust. 2011;194(8):387–91.
31. Inrig JK, Califf RM, Tasneem A, Vegunta RK, Molina C, Stanifer JW, Chiswell K, Patel UD. The landscape of clinical trials in nephrology: a systematic review of Clinicaltrials.gov. Am J Kidney Dis. 2014 May; 63(5):771–80.
32. Alexander K, Kong DF, Starr AZ, Kramer J, Chiswell K, Tasneem A, Califf RM. Portfolio of clinical research in adult cardiovascular disease as reflected in ClinicalTrials.gov. J Am Heart Assoc. 2013 Sep 26;2(5):e000009.
33. Turner EH, Matthews AM, Linardatos E, Tell RA, Rosenthal R. Selective publication of antidepressant trials and its influence on apparent efficacy. N Engl J Med. 2008 Jan 17;358(3):252–60.
34. Zarin DA, Tse T. Trust but verify: trial registration and determining fidelity to the protocol. Ann Intern Med. 2013 Jul 2;159(1):65–7.
35. Tasneem A, Aberle L, Ananth H, Chakraborty S, Chiswell K, McCourt B, Pietrobon R. The database for aggregate analysis of ClinicalTrials.gov (AACT) and subsequent regrouping by clinical specialty. PLoS One. 2012 Mar 16;7(3):e33677.
36. Breast Cancer Trials. About Breast Cancer Trials [Internet]. [cited 2016 Jul 25]. Available from: *https://www.breastcancertrials.org/BCTIncludes/WhoWeAre/AboutUs.html.*
37. Berlin JA, Morris S, Rockhold F, Askie L, Ghersi D, Waldstreicher J. Bumps and bridges on the road to responsible sharing of clinical trial data. Clinical Trials. 2014 Feb;11(1):7–12.
38. Becker JE, Krumholz HM, Ben-Josef G, Ross JS. Reporting of results in ClinicalTrials.gov and high-impact journals. JAMA. 2014 Mar 12;311(10):1063–5.
39. Mathieu S, Boutron I, Moher D, Altman DG, Ravaud P. Comparison of registered and published primary outcomes in randomized controlled trials. JAMA. 2009 Sep 2;302(9):977–84.
40. Zarin DA, Tse T, Williams RJ, Califf RM, Ide NC. The ClinicalTrials.gov results database—update and key issues. N Engl J Med. 2011;364(9):852–60.
41. Riveros C, Dechartres A, Perrodeau E, Haneef R, Boutron I, Ravaud P. Timing and completeness of trial results posted at ClinicalTrials.gov and published in journals. PLoS Med. 2013 Dec; 10(12):e1001566.
42. Ross JS, Tse T, Zarin DA, Xu H, Krumholz HM. Publication of NIH funded trials registered in ClinicalTrials.gov: cross-sectional analysis. BMJ. 2012 Jan 3;344:d7292.
43. Gordon D, Taddei-Peters W, Mascette A, Antman M, Kaufmann PG, Lauer MS. Publication of trials funded by the National Heart, Lung, and Blood Institute. N Engl J Med. 2013 Nov 14; 369(20):1926–34.
44. Wedzicha JA, Banerji D, Chapman KR, Vestbo J, Roche N, Ayers RT, Thach C, Fogel R, Patalano F, Vogelmeier CF; FLAME Investigators. Indacaterol-Glycopyrronium versus Salmeterol-Fluticasone for COPD. N Engl J Med. 2016 Jun 9;374(23):2222–34.
45. Whittington CJ, Kendall T, Fonagy P, Cottrell D, Cotgrove A, Boddington E. Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data. Lancet. 2004 Apr 24;363(9418):1341–5.
46. Rogawski MA, Federoff HJ. Disclosure of clinical trial results when product development is abandoned. Sci Transl Med. 2011 Sep 28;3(102):102cm29.
47. Institute of Medicine (US). Sharing clinical trial data: maximizing benefits, minimizing risk. Washington (DC): National Academies Press. 2015.
48. Earley A, Lau J, Uhlig K. Haphazard reporting of deaths in clinical trials: a review of cases of ClinicalTrials.gov records and matched publications-a cross-sectional study. BMJ Open. 2013 Jan 18;3(1). pii: e001963.
49. Chan A, Tetzlaff JM, Altman DG, Laupacis A, Gotzsche PC, Krleža-Jerić K, Hrobjartsson A, Mann H, Dickersin K, Berlin J, Dore C, Parulekar W, Summerskill W, Goves T, Schulz K, Sox H, Rockhold RV, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158:200–207.

50. Finfer S, Bellomo R. Why publish statistical analysis plans? Crit Care Resusc. 2009 Mar;11(1):5–6.

51. Ioannidis JP. Effectiveness of antidepressants: an evidence myth constructed from a thousand randomized trials? Philos Ethics Humanit Med. 2008 May 27;3:14.

52. Vedula SS, Bero L, Scherer RW, Dickersin K. Outcome reporting in industry-sponsored trials of gabapentin for off-label use. N Engl J Med. 2009 Nov 12; 361(20):1963–71.

53. Chan AW, Laupacis A, Moher D. Registering results from clinical trials. JAMA. 2010 Jun 2;303(21):2138–9; author reply 2139.

54. Dwan K, Altman DG, Clarke M, Gamble C, Higgins JP, Sterne JA, Williamson PR, Kirkham JJ. Evidence for the selective reporting of analyses and discrepancies in clinical trials: a systematic review of cohort studies of clinical trials. PLoS Med. 2014 Jun 24;11(6):e1001666.

55. Miller JD. Registering clinical trial results: the next step. JAMA. 2010 Feb 24; 303(8):773–4.

56. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH harmonised tripartite guideline e3: structure and content of study reports; 1995 Nov 30. Available from: *http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/E3_Guideline.pdf.*

57. Hey SP, Kesselheim AS. An uninformative truth: the logic of Amarin's off-label promotion. PLOS Medicine. 2016 Mar 15;13(3):e1001978.

58. Robertson CT. When Truth Cannot Be Presumed: The Regulation of Drug Promotion Under An Expanding First Amendment. 94 B.U. L. REV. 545, 560–61 (2014).

59. Kapczynski A. Free speech and pharmaceutical regulation—fishy business. JAMA Inter Med. 2016 Mar;176(3):295–6.

60. Avorn J, Sarpatwari A, Kesselheim AS. Forbidden and permitted statements about medications—loosening the rules. N Engl J Med. 2015 Sep 3;373(10):967–73.

61. De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, Kotzin S, Laine C, Marusic A, Overbeke JPM, Schroeder TV, Sox HC, Weyden VD. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. N Engl J Med. 2004 Sep 16;351(12):1250–1. *http://www.ncbi.nlm.nih.gov/pubmed/15356289.*

62. Taichman DB, Backus J, Baethge C, Bauchner H, de Leeuw PW, Drazen JM, Fletcher J, Frizelle FA, Groves T, Haileamlak A, James A, Laine C, Peiperl L, Pinborg A, Sahni P, Wu S. Sharing clinical trial data–a proposal from the International Committee of Medical Journal Editors. N Engl J Med. 2016 Jan 28;374(4):384–6.

63. U.S. Department of Health and Human Services, National Institutes of Health, National Library of Medicine. Meetings: Expansion of the Clinical Trails Registry and Results Databank. [Internet]. 2009 Mar 23 [cited 2016 August 30]. Available from *https://www.regulations.gov/document?D=NIH-2009-0002-0001.*

64. U.S. Department of Health and Human Services, National Institutes of Health, National Library of Medicine. Memorandum to file: notice of proposed rulemaking, FDAAA, Title VIII: clinical trials registration and results submission regarding synopsis of selected public comments [Internet]. 2012 Aug 23 [cited 2016 August 5]. Available from: *http://www.regulations.gov/#!docketDetail;D=NIH-2009-0002.*

65. National Institutes of Health (US). Draft policy on dissemination of NIH-funded clinical trial information. Washington (DC): **Federal Register**/NIH Guide for Grants and Contracts; 2014 Nov 19 and 2015 February 13. No. NOT–OD–15–019; 2015 Feb 13;80(30):8096–98.

66. National Institutes of Health (US). Compendium of Public Comments on the Draft NIH Policy on Dissemination [Internet]. Cited 2016 August 31. Available from: *http://osp.od.nih.gov/sites/default/files/resources/Clinical%20Trials%20Dissemination%20Policy%20Combined%20Comments_2.0.pdf*].

67. European Union. Communication from the Commission. Guidance on the information concerning pediatric clinical trials to be entered into the EU Database on Clinical Trials (EudraCT) and on the information to be made public by the European Medicines Agency (EMEA), in accordance with Article 41 of Regulation (EC) No 1901/2006. Official Journal of the European Union. C 28: 4; 2009 Feb 4 [cited 2016 Jul 25]. Available from: *http://ec.europa.eu/health/files/eudralex/vol-10/2009_c28_01/2009_c28_01_en.pdf.*

68. European Commission. Communication from the Commission regarding the guideline on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No 726/2004, Official Journal of the European Union. C168: 2; 2008 Jul 7 [cited 2016 Jul 25]. Available from: *http://ec.europa.eu/health/files/eudralex/vol-10/2008_07/c_16820080703en00030004_en.pdf.*

69. European Commission. List of fields to be made public from EudraCT for Pediatric Clinical Trials in accordance with Article 41 of Regulation (EC) No 1901/2006 and its implementing guideline 2009/C28/01; 2009 Feb 4 [cited 2016 Jul 25]. Available from: *http://ec.europa.eu/health/files/eudralex/vol-10/2009_02_04_guidelines_paed_en.pdf.*

70. EU Clinical Trials Register [Internet]. Canary Wharf, London; [cited 2016 Aug 5]. Available from: *https://www.clinicaltrialsregister.eu/.*

71. European Medicines Agency [Internet]. European Medicines Agency; c1995–2016. European Medicines Agency launches a new version of EudraCT; 10 Nov 13 [cited 2016 Aug 8]; [about 2 screens]. Available from: *http://www.ema.europa.eu/ema/index.jsp?curl=pages%2Fnews_and_events%2Fnews%2F2013%2F10%2Fnews_detail_001918.jsp.*

72. Risk Communication Advisory Committee, Food and Drug Administration (US). Presentations, transcript, minutes; 2009 Nov. Available from: *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/ucm313608.htm.*

73. World Health Organization (WHO). International Clinical Trial Registry Platform Trial Registration Data Set (Version 1.2.1) [Internet] [cited 2016 Aug 5]. Available from: *http://www.who.int/ictrp/network/trds/en/.*

74. WHO: World Health Organization [Internet]. World Health Organization; 2016. WHO statement on public disclosure of clinical trial results; [cited 2016 Aug 8]; [about 3 screens]. Available from: *http://www.who.int/ictrp/results/reporting/en/.*

75. International Health Terminology Standards Development Organization. SNOMED CT [Internet] [cited 2016 Aug 8]. Available from: *http://www.ihtsdo.org/snomed-ct.*

76. Healthcare Information Technology Standards Panel (US). HITSP: enabling healthcare interoperability [updated 30 April 2010; cited 2016 Aug 8]. Available from: *http://www.hitsp.org.*

77. Medical Subject Headings (MeSH®) Unified Medical Language System (UMLS) Metathesaurus [Internet]. United States: National Institutes of Health, National Library of Medicine (US). 1999—[updated 2016 Jun 20; cited 2016 Aug 8]. Available from: *https://www.nlm.nih.gov/mesh/.*

78. Food and Drug Administration, [Internet]. U.S. Department of Health and Human Services; 2002. Guidance for industry: information program on clinical trials for serious or life-threatening diseases and conditions [cited 2016 Aug 8]. Available from: *http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126838.pdf.*

79. Food and Drug Administration [Internet]. U.S. Department of Health and Human Services; 2004. Guidance for industry: information program on clinical trials for serious or life-threatening diseases and conditions [cited 2016 Aug 8]. Available from: *http://www.fda.gov/downloads/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/UCM077229.pdf.*

80. Office for Human Research Protections [Internet]. U.S. Department of Health and Human Services. Unanticipated Problems Involving Risks and Adverse Events Guidance [cited 2016 Aug 8]. Available from: *http://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/.*

81. International Conference on Harmonisation of Technical Requirements for Registration of

Pharmaceuticals for Human Use [Internet]. ICH Harmonised Tripartite Guideline: Guideline for good clinical practice E6(R1) [1996 Jun 10; cited 2016 Aug 8]. Available from: *http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html.*

82. Food and Drug Administration. U.S. Department of Health and Human Services; 2013. Investigational Device Exemptions (IDEs) for early feasibility medical device clinical studies, including certain First in Human (FIH) studies [cited 2016 Aug 8]. Available from: *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279103.pdf.*

83. Food and Drug Administration. U.S. Department of Health and Human Services; 2006. Guidance for sponsors, institutional review boards, clinical investigators and FDA staff: guidance on informed consent for in vitro diagnostic device studies using leftover human specimens that are not individually identifiable [cited 2016 Aug 8]. Available from *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf.*

84. Li T, Yu T, Hawkins BS, Dickersin K (2015) design, analysis, and reporting of crossover trials for inclusion in a meta-analysis. PLoS One. 2015;10(8): e0133023.

85. National Library of Medicine, National Institutes of Health. Protocol Data Element Definitions. Washington (DC): U.S. Department of Health and Human Services; 2015. Available from *https://prsinfo.clinicaltrials.gov/definitions.html.*

86. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use [Internet]. Choice of control group and related issues in clinical trials (ICH E10) [2000 July 20; cited 2016 Aug 8]. Available from *http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E10/Step4/E10_Guideline.pdf.*

87. National Library of Medicine. National Institutes of Health. Medical Literature Analysis and Retrieval System Online, Clinical Trial Registry Numbers in MEDLINE®/PubMed® Records [Internet]. U.S. Department of Health and Human Services. [updated 2008 Jan 17; cited 2016 Aug 8]. Available from: *http://www.nlm.nih.gov/bsd/policy/clin_trials.html.*

87a. National Library of Medicine. National Institutes of Health. Grants and Funding [Internet]. 2013 Mar 13. [Cited 2016 Sep 5]. Available from: *http://grants.nih.gov/grants/glossary.htm#ProgramDirector/PrincipalInvestigator(PD/PI)).*

88. International Organization for Standardization [Internet]. Clinical investigation of medical devices for human subjects—good clinical practice (ISO 14155:2011) [updated 2016 Jun 17; cited 2016 Aug 8]. Available from: *http://www.iso.org/iso/catalogue_detail?csnumber=45557.*

89. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th rev. ed. Washington, DC: American Psychiatric Association. 2013.

90. National Library of Medicine, National Institutes of Health. Elaboration of Definitions. Washington (DC): U.S. Department of Health and Human Services; 2009 Mar 9. Available from: *https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf.*

91. Board of Regents Working Group. Final report to the NLM Board of Regents from its Working Group on health data standards. National Library of Medicine, National Institute of Health (US); 2009 Apr. Available from: *https://www.nlm.nih.gov/od/bor/past-working-groups.html.*

92. Secretary's Advisory Committee on Human Research Protections, Department of Health and Human Services (US). Meeting Presentations; 2011 Mar. Available from: *http://wayback.archive-it.org/org-745/20150824190405/http://www.hhs.gov/ohrp/sachrp/mtgings/mtg03-11/20110308pfds.html.*

93. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. Ann Intern Med. 2010 Jun 1;152(11):726–32. Available from: *http://www.consort-statement.org/checklists/view/32-consort/78-interventions.*

94. Fairman KA, Curtiss FR. What should be done about bias and misconduct in clinical trials? J Manag Care Pharm. 2009 Mar;15(2):154–60.

95. Food and Drug Administration (US). Evaluation of sex-specific data in medical device clinical studies—guidance for industry and Food and Drug Administration staff. Washington (DC): U.S. Department of Health and Human Services; 2014. Available from: *http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm283453.htm.*

96. Institute of Medicine. Exploring the Biological Contributions to Human Health: Does Sex Matter? Washington, DC: The National Academies Press (US); 2001. Doi:10.17226/10028.

97. National Library of Medicine, National Institutes of Health. Results data element definitions. Washington (DC): U.S. Department of Health and Human Services; 2015. Available from *https://prsinfo.clinicaltrials.gov/results_definitions.html.*

98. About ICMJE [Internet]. International Committee of Medical Journal Editors. Clinical Trials Registration [cited 2016 Aug 8]. Available from: *http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/.*

98a. European Commission. European Clinical Trials Database, Results Related Documentation [Internet]. 2016 Jul 15 [cited 2016 Sep 5]. Available from: *https://eudract.ema.europa.eu/result.html.*

99. MedDRA: Medical Dictionary for Regulatory Affairs [Internet]. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. c1990 [cited 2016 Aug 8]. Available from: *http://www.meddra.org.*

100. MedDRA [Internet]. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. About MedDRA [cited 2016 Aug 8]. Available from: *http://www.meddra.org/about-meddra/history.*

101. NCIthesaurus [Internet]. National Cancer Institute (US). Available from: *https://ncit.nci.nih.gov/ncitbrowser/.*

102. Rief W, Nestoriuc Y, von Lilienfeld-Toal A, Dogan I, Schreiber F, Hofmann SG, Barsky AJ, Avorn J. Differences in adverse effect reporting in placebo groups in SSRI and tricyclic antidepressant trials: A systematic review and meta-analysis. Drug Saf. 2009;32(11):1041–56.

103. Ioannidis JP, Evans SJ, Gøtzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D; CONSORT Group. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med. 2004 Nov 16;141(10):781–8.

104. Food and Drug Administration (US). Guidance on conducting a clinical safety review of a new product application and preparing a report on the review. Washington (DC): U.S. Department of Health and Human Services; 2005. Available from: *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072974.pdf.*

105. Sherman RB, Woodcock J, Norden J, Grandinetti C, Temple RJ. New FDA regulation to improve safety reporting in clinical trials. N Engl J Med. 2011 Jul 7; 365(1):3–5.

106. Hillman SL, Mandrekar SJ, Bot B, DeMatteo RP, Perez EA, Ballman KV, Nelson H, Buckner JC, Sargent DJ. Evaluation of the value of attribution in the interpretation of adverse event data: a North Central Cancer Treatment Group and American College of Surgeons Oncology Group investigation. J Clin Oncol. 2010 Jun 20;28(18):3002–7.

107. Mukherjee SD, Coombes, ME, Levine M, Cosby J, Kowaleski B, Arnold A. A qualitative study evaluating causality attribution for serious adverse events during early phase oncology clinical trials. Invest New Drugs. 2011 Oct;29(5):1013–20.

108. Rief W, Avorn J, Barsky AJ. Medication-attributed adverse effects in placebo groups. Arch Intern Med. 2006 Jan 23;166(2):155–60.

109. MedDRA [Internet]. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. What's new? MedDRA Version 19.0. [updated 2016 Mar; cited 2016 Aug 8]. Available from: *http://www.meddra.org/sites/default/files/guidance/file/whats new_19_0_english.pdf.*

110. Mello MM, Clarridge BR, Studdert DM. Academic medical centers' standards for clinical trial agreements with industry. N Engl J Med. 2005 May 26;352(21):2202–10.

111. ClinicalTrials.gov [Internet]. U.S. National Institutes of Health. How to submit your results [updated 2014 Dec; cited 2016 Aug 8]. Available from: *https://clinicaltrials.gov/ct2/manage-recs/how-report#ScientificInformation.*

111a. Schwartz LM, Woloshin S, Zheng E, Tse T, Zarin DA. ClinicalTrials.gov and Drugs@FDA: A Comparison of Results Reporting for New Drug Approval Trials. Ann Intern Med. 2016 Jun 14.

112. Grants and Funding [Internet]. National Institutes of Health. Frequently asked questions: FDAAA—further resources for NIH grantees [updated 2011 April 25; cited 2016 August 8]. Available from: *http://grants.nih.gov/clinicaltrials_fdaaa/faq.htm#836.*

113. Wong H, Jessup A. Examination of clinical trial costs and barriers for drug development. Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services (US) [updated 2014; cited 2016 Aug 8]. Available from: *https://aspe.hhs.gov/sites/default/files/pdf/77166/rpt_erg.pdf.*

114. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ. 2016 May;47:20–3.

115. National Institutes of Health (US). Estimates of funding for various research, condition, and disease categories [updated 2016 Feb 10; cited 2016 July 27]. Available from: *https://report.nih.gov/categorical_spending.aspx.*

116. McCarthy K, Godlew BJ. ClinicalTrials.gov: a questionnaire of industry experiences and perceptions. Drug Information Journal. May 2010 44: 233–241.

117. White, Sarah A. (Human Research Quality Improvement Program, Partners' Healthcare, Boston Massachusetts). Conversation with: Zarin, Deborah A (National Library of Medicine, National Institutes of Health, Bethesda, MD). 2016 July 11.

118. O'Reilly EK, Hassell NJ, Snyder DC, Natoli S, Liu I, Rimmler J, Amspacher V, Burnett BK, Parrish AB, Berglund JP, Stacy M. ClinicalTrials.gov reporting: strategies for success at an academic health center. Clin Transl Sci. 2015 Feb;8(1):48–51.

119. North American Industry Classification System, 2012 NAICS Definitions [Internet]. U.S. Census Bureau [cited 2016 Aug 10]. Available from: *http://www.census.gov/cgi-bin/sssd/naics/naicsrch?chart_code=31&search=2012%20NAICS%20Search.*

120. Table of Small Business Size Standards Matched to North American Industry Classification System Codes [Internet]. U.S. Small Business Administration. 2016 Feb 26 [cited 2016 Aug 10]. Available from: *https://www.sba.gov/contracting/getting-started-contractor/make-sure-you-meet-sba-size-standards/table-small-business-size-standards.*

121. U.S. Census Bureau Official Site [Internet]. Washington (DC): Economic census; 2012 [cited 2016 Aug 10]. Available from: *https://www.census.gov/econ/census/.*

122. U.S. Census Bureau Official Site [Internet]. Washington (DC): American FactFinder database; 2012 [cited 2016 Aug 10]. Available from: *http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2012_US_31SG2&prodType=table.*

List of Subjects in 42 CFR Part 11

Biologics, Clinical trial, Data bank, Drugs, Human subjects research, Medical devices, Medical research, Registry, Reporting and recordkeeping requirements, Results information.

Regulatory Text

For the reasons stated in this preamble, the U.S. Department of Health and Human Services amends Title 42, Chapter I of the Code of Federal Regulations by adding Part 11 to subchapter A to read as follows:

PART 11—CLINICAL TRIALS REGISTRATION AND RESULTS INFORMATION SUBMISSION

Subpart A—General Provisions

Sec.

11.2 What is the purpose of this part?
11.4 To whom does this part apply?
11.6 What are the requirements for the submission of truthful information?
11.8 In what format must clinical trial information be submitted?
11.10 What definitions apply to this part?

Subpart B—Registration

11.20 Who must submit clinical trial registration information?
11.22 Which applicable clinical trials must be registered?
11.24 When must clinical trial registration information be submitted?
11.28 What constitutes clinical trial registration information?
11.35 By when will the NIH Director post clinical trial registration information submitted under § 11.28?

Subpart C—Results Information Submission

11.40 Who must submit clinical trial results information?
11.42 For which applicable clinical trials must clinical trial results information be submitted?
11.44 When must clinical trial results information be submitted for applicable clinical trials subject to § 11.42?
11.48 What constitutes clinical trial results information?
11.52 By when will the NIH Director post submitted clinical trial results information?
11.54 What are the procedures for requesting a waiver of the requirements for clinical trial results information submission?

Subpart D—Additional Submission of Clinical Trial Information

11.60 What requirements apply to the voluntary submission of clinical trial information for clinical trials of FDA-regulated drug products (including biological products) and device products?
11.62 What requirements apply to applicable clinical trials for which submission of clinical trial information has been determined by the Director to be necessary to protect the public health?
11.64 When must clinical trial information submitted to *ClinicalTrials.gov* be updated or corrected?

Subpart E—Potential Legal Consequences of Non-Compliance

11.66 What are potential legal consequences of not complying with the requirements of this part?

Authority: 42 U.S.C. 282(i); 42 U.S.C. 282(j); 5 U.S.C. 301; 42 U.S.C. 286(a); 42 U.S.C. 241(a); 42 U.S.C. 216(b).

Subpart A—General Provisions

§ 11.2 What is the purpose of this part?

This part implements section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) by providing requirements and procedures for the submission of clinical trial information for certain applicable clinical trials and other clinical trials to the Director of the National Institutes of Health (NIH) to be made publicly available via ClinicalTrials.gov, the Internet-accessible clinical trial registry and results data bank established by the National Library of Medicine (NLM) at *https://clinicaltrials.gov.*

§ 11.4 To whom does this part apply?

(a) This part applies to the responsible party for an applicable clinical trial that is required to be registered under § 11.22, a clinical trial for which clinical trial registration information or clinical trial results information is submitted voluntarily in accordance with § 11.60, or an applicable clinical trial that is required by the Director to have clinical trial information submitted to protect the public health under § 11.62.

(b) The responsible party must communicate the identity and contact information of the responsible party to the Director by submitting the Responsible Party, by Official Title and Responsible Party Contact Information data elements under § 11.28(a)(2)(iii)(B) and (a)(2)(iv)(F) as part of the clinical trial information submitted at the time of registration. Changes must be communicated to the Director by updating information in accordance with § 11.64(a).

(c) *Determination of responsible party.* For purposes of this part, each applicable clinical trial or other clinical trial must have one responsible party. With respect to a clinical trial, the sponsor of the clinical trial will be considered the responsible party unless and until a principal investigator has been designated the responsible party, in accordance with paragraph (c)(2) of this section. With respect to a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party is the entity that the U.S. Food and Drug Adminstration (FDA), under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3601), orders to conduct the pediatric postmarket surveillance of a device product.

(1) *Determination of sponsor.* For purposes of this part, each applicable clinical trial or other clinical trial must have one sponsor.

(i) When an applicable clinical trial or other clinical trial is conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE holder will be considered the sponsor.

(ii) When an applicable clinical trial or other clinical trial is not conducted under an IND or IDE, the single person or entity who initiates the trial, by preparing and/or planning the trial, and who has authority and control over the trial, will be considered the sponsor.

(2) *Designation of a principal investigator as the responsible party.*

(i) The sponsor may designate a principal investigator as the responsible party if such principal investigator meets all of the following requirements:

(A) Is responsible for conducting the trial;

(B) Has access to and control over the data from the trial;

(C) Has the right to publish the results of the trial; and

(D) Has the ability to meet all of the requirements for submitting and updating clinical trial information as specified in this part.

(ii) With regard to an applicable clinical trial or other clinical trial, a designation by the sponsor under paragraph (c)(2)(i) of this section shall consist of the sponsor obtaining from the principal investigator an acknowledgment of the principal investigator's responsibilities under this part as responsible party, and the principal investigator acknowledging the designation as responsible party to the Director in the format specified at *https://prsinfo.clinicaltrials.gov.*

(3) *Withdrawal of the designation of a principal investigator as the responsible party.* In the event that a principal investigator who has been designated the responsible party no longer meets or is no longer able to meet all the requirements for being so designated under paragraph (c)(2)(i) of this section, the sponsor must withdraw the designation in the format specified at *https://prsinfo.clinicaltrials.gov,* at which time the sponsor will be considered the responsible party unless and until the sponsor makes a new designation in accordance with paragraph (c)(2) of this section.

§ 11.6 What are the requirements for the submission of truthful information?

The clinical trial information submitted by a responsible party under this part shall not be false or misleading in any particular. A responsible party who submits false and/or misleading information is subject to civil monetary penalties and/or other civil or criminal remedies available under U.S. law.

§ 11.8 In what format must clinical trial information be submitted?

Information submitted under this part must be submitted electronically to ClinicalTrials.gov, in the format specified at *https://prsinfo.clinicaltrials.gov.*

§ 11.10 What definitions apply to this part?

(a) The following definitions apply to terms used in this part:

Adverse event means any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. See also the definition of "serious adverse event."

Applicable clinical trial means an applicable device clinical trial or an applicable drug clinical trial. Expanded access use under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is not an applicable clinical trial.

Applicable device clinical trial means:

(1) A prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes);

(2) A pediatric postmarket surveillance of a device product as required under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3601); or

(3) A clinical trial of a combination product with a device primary mode of action under 21 CFR part 3, provided that it meets all other criteria of the definition under this part.

Applicable drug clinical trial means a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 and "phase 1" has the meaning given in 21 CFR 312.21. A clinical trial of a combination product with a drug primary mode of action under 21 CFR part 3 is also an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part.

Approved drug means a drug product that is approved for any use under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product licensed for any use under section 351 of the Public Health Service Act (42 U.S.C. 262).

Approved or cleared device means a device product that is cleared for any use under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360(k)) or approved for any use under sections 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360e, 360j(m)).

Arm means a pre-specified group or subgroup of human subject(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.

Clinical study means research according to a protocol involving one or more human subjects to evaluate biomedical or health-related outcomes, including interventional studies and observational studies.

Clinical trial means a clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health-related outcomes.

Clinical trial information means the data elements, including clinical trial registration information and clinical trial results information, that the responsible party is required to submit to *ClinicalTrials.gov*, as specified in section 402(j) of the Public Health

Service Act (42 U.S.C. 282(j)) and this part.

Clinical trial registration information means the data elements that the responsible party is required to submit to *ClinicalTrials.gov*, as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) or § 11.28, as applicable.

Clinical trial results information means the data elements that the responsible party is required to submit to *ClinicalTrials.gov*, as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and (I)) or § 11.48, as applicable. If a responsible party submits clinical trial results information voluntarily for a clinical trial, clinical trial results information also means § 11.60(b)(2)(i)(B) or § 11.60(c)(2)(i)(B), as applicable.

Comparison group means a grouping of human subjects in a clinical trial that is or may be used in analyzing the results data collected during the clinical trial.

Completion date means, for a clinical trial, including an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. In the case of clinical trials with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes. For a pediatric postmarket surveillance of a device product that is not a clinical trial, completion date means the date on which the final report of the pediatric postmarket surveillance of the device product is submitted to FDA. For purposes of this part, completion date is referred to as "primary completion date."

Control or controlled means, with respect to a clinical trial, that data collected on human subjects in the clinical trial will be compared to concurrently collected data or to non-concurrently collected data (*e.g.,* historical controls, including a human subject's own baseline data), as reflected in the pre-specified primary or secondary outcome measures. For purposes of this part, all clinical trials with one or more arms and pre-specified outcome measure(s) are controlled.

Device means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

Director means the NIH Director or any official of NIH to whom the NIH Director delegates authorities granted in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

Drug means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) or a biological product as defined in section 351 of the Public Health Service Act (42 U.S.C. 262).

Enroll or enrolled means a human subject's, or their legally authorized representative's, agreement to participate in a clinical trial following completion of the informed consent process, as required in 21 CFR part 50 and/or 45 CFR part 46, as applicable. For the purposes of this part, potential subjects who are screened for the purpose of determining eligibility for a trial, but do not participate in the trial, are not considered enrolled, unless otherwise specified by the protocol.

Human subjects protection review board means an institutional review board (IRB) as defined in 21 CFR 50.3 or 45 CFR 46.102, as applicable, that is responsible for assuring the protection of the rights, safety, and well-being of human subjects involved in a clinical trial and is adequately constituted to provide assurance of that protection. An IRB may also be known as an "independent ethics committee."

Interventional means, with respect to a clinical study or a clinical investigation, that participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health-related outcomes.

Investigational Device Exemption (IDE) has the meaning given in 21 CFR part 812.

Investigational New Drug Application (IND) has the meaning given in 21 CFR 312.3.

NCT number means the unique identification code assigned to each record in *ClinicalTrials.gov,* including a record for an applicable clinical trial, a clinical trial, or an expanded access program.

Ongoing means, with respect to a clinical trial of a drug product (including a biological product) or a device product and to a date, that one or more human subjects is enrolled in the clinical trial, and the date is before the primary completion date of the clinical trial. With respect to a pediatric postmarket surveillance of a device product, ongoing means a date between the date on which FDA approves the plan for conducting the surveillance and the date on which the final report is submitted to FDA.

Outcome measure means a pre-specified measurement that will be used to determine the effect of an experimental variable on the human subject(s) in a clinical trial. See also the definitions of "primary outcome measure" and "secondary outcome measure."

Pediatric postmarket surveillance of a device product means the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information conducted under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) about a marketed device product that is expected to have significant use in patients who are 21 years of age or younger at the time of diagnosis or treatment. A pediatric postmarket surveillance of a device product may be, but is not always, a clinical trial.

Primary completion date means, for purposes of this part, "completion date." See the definition of "completion date."

Primary outcome measure means the outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation. Most clinical trials have one primary outcome measure, but a clinical trial may have more than one. For purposes of this part, "primary outcome" has the same meaning as primary outcome measure.

Principal investigator means the individual who is responsible for the overall scientific and technical direction of the study.

Protocol means the written description of the clinical trial, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations.

Responsible party means, with respect to a clinical trial, the sponsor of the clinical trial, as defined in 21 CFR 50.3; or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this part for the submission of clinical trial information. For a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party is the entity who FDA orders to conduct the pediatric postmarket surveillance of the device product.

Secondary outcome measure means an outcome measure that is of lesser importance than a primary outcome measure, but is part of a pre-specified analysis plan for evaluating the effects of the intervention or interventions under investigation in a clinical trial and is not specified as an exploratory or other measure. A clinical trial may have more than one secondary outcome measure. For purposes of this part, "secondary outcome" has the same meaning as secondary outcome measure.

Secretary means the Secretary of Health and Human Services or any other official(s) to whom the Secretary delegates the authority contained in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

Serious adverse event means an adverse event that results in any of the following outcomes: Death, a life-threatening adverse event as defined in 21 CFR 312.32, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the human subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of a substance use disorder.

Sponsor means either a "sponsor" or "sponsor-investigator," as each is defined in 21 CFR 50.3.

Study completion date means, for a clinical trial, the date the final subject was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (*e.g.,* last subject's last visit), whether the clinical trial concluded according to the pre-specified protocol or was terminated.

U.S. FDA-regulated device product means, for purposes of this part, a device product subject to section 510(k), 515, 520(m), or 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m), 21 U.S.C. 360l).

U.S. FDA-regulated drug product means, for purposes of this part, a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act or a biological product subject to section 351 of the Public Health Service Act (21 U.S.C. 355, 42 U.S.C. 262).

(b) The following definitions apply to data elements of clinical trial information referenced in this part, unless otherwise specified:

(1) *Brief Title* means a short title of the clinical trial written in language intended for the lay public, including any acronym or abbreviation used publicly to identify the clinical trial.

(2) *Official Title* means the title of the clinical trial, corresponding to the title of the protocol.

(3) *Brief Summary* means a short description of the clinical trial, including a brief statement of the clinical trial's hypothesis, written in language intended for the lay public.

(4) *Primary Purpose* means the main objective of the intervention(s) being evaluated by the clinical trial.

(5) *Study Design* means a description of the manner in which the clinical trial will be conducted, including the following information:

(i) *Interventional Study Model.* The strategy for assigning interventions to human subjects.

(ii) *Number of Arms.* The number of arms in the clinical trial. For a trial with multiple periods or phases that have different numbers of arms, it means the maximum number of arms during all periods or phases.

(iii) *Arm Information.* A description of each arm of the clinical trial that indicates its role in the clinical trial, provides an informative title, and, if necessary, additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial.

(iv) *Allocation.* The method by which human subjects are assigned to arms in a clinical trial.

(v) *Masking.* The party or parties, if any, involved in the clinical trial who are prevented from having knowledge of the interventions assigned to individual human subjects.

(6) *Study Phase* means, for a clinical trial of a drug product (including a biological product), the numerical phase of such clinical trial, consistent with terminology in 21 CFR 312.21, such as phase 2 or phase 3, and in 21 CFR 312.85 for phase 4 studies.

(7) *Study Type* means the nature of the investigation or investigational use for which clinical trial information is being submitted, *e.g.,* interventional, observational.

(8) *Pediatric Postmarket Surveillance of a Device Product* means a clinical trial or study that includes a U.S. FDA-regulated device product as an intervention and is a pediatric postmarket surveillance of a device product ordered under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 369l).

(9) *Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study* means the name(s) of the disease(s) or condition(s) studied in the clinical trial, or the focus of the clinical trial. Use, if available, appropriate descriptors from NLM's Medical Subject Headings (MeSH)-controlled vocabulary thesaurus or terms from another vocabulary, such as the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT), that has been mapped to MeSH within the Unified Medical Language System (UMLS) Metathesaurus.

(10) *Intervention Name(s)* means a brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical trial. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used.

(11) *Other Intervention Name(s)* means other current and former name(s) or alias(es), if any, different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention(s), including, but not limited to, past or present names such as brand name(s), or serial numbers.

(12) *Intervention Description* means details that can be made public about the intervention, other than the Intervention Name(s) and Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions studied in the same or another clinical trial. For example, interventions involving drugs may include dosage form, dosage, frequency, and duration.

(13) *Intervention Type* means, for each intervention studied in the clinical trial, the general type of intervention, *e.g.,* drug, biological/vaccine, or, device.

(14) *Device Product Not Approved or Cleared by U.S. FDA* means that at least one device product studied in the clinical trial has not been previously approved or cleared by FDA for one or more uses.

(15) *Product Manufactured in and Exported from the U.S.* means that any drug product (including a biological product) or device product studied in the clinical trial is manufactured in the United States or one of its territories and exported for study in a clinical trial in another country.

(16) *Study Start Date* means the estimated date on which the clinical trial will be open for recruitment of human subjects, or the actual date on which the first human subject was enrolled.

(17) *Primary Completion Date* means the estimated or actual primary completion date. If an estimated primary completion date is used, the responsible party must update the Primary Completion Date data element once the clinical trial has reached the primary completion date to reflect the actual primary completion date.

(18) *Enrollment* means the estimated total number of human subjects to be enrolled (target number) or the actual total number of human subjects that are enrolled in the clinical trial. Once the trial has reached the primary completion date, the responsible party must update the Enrollment data element to reflect the actual number of human subjects enrolled in the clinical trial.

(19) *Primary Outcome Measure Information* means a description of each primary outcome measure, to include the following information:

(i) Name of the specific primary outcome measure;

(ii) Description of the metric used to characterize the specific primary outcome measure; and

(iii) Time point(s) at which the measurement is assessed for the specific metric used.

(20) *Secondary Outcome Measure Information* means a description of each secondary outcome measure, to include the following information:

(i) Name of the specific secondary outcome measure;

(ii) Description of the metric used to characterize the specific secondary outcome measure; and

(iii) Time point(s) at which the measurement is assessed for the specific metric used.

(21) *Eligibility Criteria* means a limited list of criteria for selection of human subjects to participate in the clinical trial, provided in terms of inclusion and exclusion criteria and suitable for assisting potential human subjects in identifying clinical trials of interest.

(22) *Sex/Gender* means the sex and, if applicable, gender of the human subjects who may participate in the clinical trial.

(23) *Age Limits* means the minimum and maximum age of human subjects who may participate in the clinical trial, provided in relevant units of time.

(24) *Accepts Healthy Volunteers* means that human subjects who do not have a disease or condition, or related conditions or symptoms, under study in the clinical trial are permitted to participate in the clinical trial.

(25) *Overall Recruitment Status* means the recruitment status for the clinical trial as a whole, based on the status of the individual sites. If at least one facility in a multi-site clinical trial has an individual site status of "recruiting," then the overall recruitment status for the trial must be "recruiting."

(26) *Why Study Stopped* means, for a clinical trial that is suspended or terminated or withdrawn prior to its planned completion as anticipated by the protocol, a brief explanation of the reason(s) why the clinical trial was stopped.

(27) *Individual Site Status* means the recruitment status of each participating facility in a clinical trial.

(28) *Availability of Expanded Access* means, for an applicable drug clinical trial of a drug product (including a biological product) that is not an approved drug product (including a biological product), and for which the responsible party is both the manufacturer of the drug product (including a biological product) and the sponsor of the applicable clinical trial:

(i) An indication of whether there is expanded access to the investigational drug product (including a biological product) under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) for those individuals who do not qualify for enrollment in the applicable clinical trial, under one or more of the following types of expanded access programs: for individual patients, including for emergency use, as specified in 21 CFR 312.310; for intermediate-size patient populations, as specified in 21 CFR 312.315; or under a treatment IND or treatment protocol, as specified in 21 CFR 312.320; and

(ii) If expanded access is available under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb), the NCT number of the expanded access record.

(29) *Name of the Sponsor* means the name of the entity or individual who is the sponsor of the clinical trial, as defined in this part.

(30) *Responsible Party, by Official Title* means an:

(i) Indication of whether the responsible party is the sponsor of the clinical trial, as that term is defined in 21 CFR 50.3; the sponsor-investigator, as that term is defined in 21 CFR 50.3; or a principal investigator designated pursuant to this part; and

(ii) Either:

(A) The official name of the entity, if the responsible party is an entity; or

(B) The official title and primary organizational affiliation of the individual, if the responsible party is an individual.

(31) *Facility Information* means, for each participating facility in a clinical trial, the following information:

(i) Facility Name, meaning the full name of the organization where the clinical trial is being conducted;

(ii) Facility Location, including city, state, country and zip code for U.S. locations (including territories of the United States) and city and country for locations in other countries; and

(iii) Either:

(A) For each facility participating in a clinical trial, Facility Contact, including the name or title, telephone number, and email address of a person to whom questions concerning the trial and enrollment at that site can be addressed; or

(B) Central Contact Person, including the name or title, toll-free telephone number, and email address of a person to whom questions concerning enrollment at any location of the trial can be addressed.

(32) *Unique Protocol Identification Number* means any unique identifier assigned to the protocol by the sponsor.

(33) *Secondary ID* means:

(i) Any identifier(s) other than the organization's unique protocol identifier or NCT number that is assigned to the clinical trial, including any unique clinical trial identifiers assigned by other publicly available clinical trial registries. If the clinical trial is funded in whole or in part by a U.S. Federal Government agency, the complete grant or contract number must be submitted as a Secondary ID.

(ii) A description of the type of Secondary ID.

(34) *U.S. Food and Drug Administration IND or IDE Number* means an indication of whether there is an IND or IDE for the clinical trial and, if so, each of the following elements:

(i) Name or abbreviation of the FDA center with whom the IND or IDE is filed;

(ii) IND or IDE number assigned by the FDA center; and

(iii) For an IND, the IND serial number, as defined in 21 CFR 312.23(e), if any, assigned to the clinical trial.

(35) *Human Subjects Protection Review Board Status* means information to indicate whether a clinical trial has been reviewed and approved by a human subjects protection review board or whether such review is not required per applicable law (*e.g.*, 21 CFR part 56, 45 CFR part 46, or other applicable regulation). Human Subjects Protection Review Board Status must be listed as "approved" if at least one human subjects protection review board has approved the clinical trial.

(36) *Record Verification Date* means the date on which the responsible party last verified the clinical trial information in the entire ClinicalTrials.gov record for the clinical trial, even if no additional or updated information was submitted at that time.

(37) *Responsible Party Contact Information* means administrative information to identify and allow communication with the responsible party by telephone, email, and regular mail or delivery service. Responsible Party Contact Information includes the name, official title, organizational affiliation, physical address, mailing address, phone number, and email address of the individual who is the responsible party or of a designated employee of the organization that is the responsible party.

(38) *Studies a U.S. FDA-regulated Device Product* means that a clinical trial studies a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)).

(39) *Studies a U.S. FDA-regulated Drug Product* means a clinical trial studies a drug product (including a biological product) subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(40) *Post Prior to U.S. FDA Approval or Clearance* means, for an applicable device clinical trial of a device product that has not been previously approved or cleared, the responsible party indicates to the Director that it is authorizing the Director, in accordance with § 11.35(b)(2)(ii), to publicly post its clinical trial registration information, which would otherwise be subject to delayed posting, as specified in § 11.35(b)(2)(i), prior to the date of FDA approval or clearance of its device product.

(41) *Study Completion Date* means the estimated or actual study completion date. Once the clinical trial has reached the study completion date, the responsible party must update the Study Completion Date data element to reflect the actual study completion date in accordance with § 11.64(a)(1)(ii)(J) .

Subpart B—Registration

§ 11.20 Who must submit clinical trial registration information?

The responsible party for an applicable clinical trial specified in § 11.22 must submit clinical trial registration information for that clinical trial.

§ 11.22 Which applicable clinical trials must be registered?

(a) *General specification.* (1) Any applicable clinical trial that is initiated after September 27, 2007, must be registered.

(2) Any applicable clinical trial that is initiated on or before September 27, 2007, and is ongoing on December 26, 2007, must be registered.

(3) *Determining the date of initiation for an applicable clinical trial.* An applicable clinical trial, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, is considered to be initiated on the date on which the first human subject is enrolled. A pediatric postmarket surveillance of a device product that is not a clinical trial is considered to be initiated on the date on which FDA approves the plan for conducting the surveillance.

(b) *Determination of applicable clinical trial for a clinical trial or study initiated on or after January 18, 2017.* A clinical trial or study that, at any point in time, meets the conditions listed in paragraph (b)(1) or (2) of this section will be considered to meet the definition of an applicable clinical trial.

(1) *Applicable device clinical trial.* A clinical trial or study that meets the conditions listed in either paragraph (b)(1)(i) or (ii) of this section is an applicable device clinical trial:

(i) The study is a pediatric postmarket surveillance of a device product as required by FDA under section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3601).

(ii) The study is a clinical trial with one or more arms that meets all of the following criteria:

(A) Study Type is interventional;

(B) Primary Purpose of the clinical trial is other than a feasibility study;

(C) The clinical trial Studies a U.S. FDA-regulated Device Product; and

(D) One or more of the following applies:

(*1*) At least one Facility Location is within the United States or one of its territories,

(*2*) A device product under investigation is a Product Manufactured in and Exported from the U.S. or one of its territories for study in another country, or

(*3*) The clinical trial has a U.S. Food and Drug Administration IDE Number.

(2) *Applicable drug clinical trial.* A clinical trial with one or more arms that meets the following conditions is an applicable drug clinical trial:

(i) Study Type is interventional;

(ii) Study Phase is other than phase 1;

(iii) The clinical trial Studies a U.S. FDA-regulated Drug Product; and

(iv) One or more of the following applies:

(A) At least one Facility Location for the clinical trial is within the United States or one of its territories,

(B) A drug product (including a biological product) under investigation is a Product Manufactured in and Exported from the U.S. or one of its territories for study in another country, or

(C) The clinical trial has a U.S. Food and Drug Administration IND Number.

§ 11.24 When must clinical trial registration information be submitted?

(a) *General.* Except as provided in paragraph (b) of this section, the responsible party for an applicable clinical trial for which submission of clinical trial registration information is required must submit the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) or § 11.28(a), as applicable, not later than December 26, 2007, or 21 calendar days after the first human subject is enrolled, whichever date is later.

(b) *Exceptions:*. (1) The responsible party for an applicable clinical trial that is a clinical trial and for which the submission of clinical trial registration information is required and that is not for a serious or life-threatening disease or condition must submit clinical trial registration information as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) or § 11.28(a), as applicable, not later than September 27, 2008, or 21 calendar days after the first human subject is enrolled, whichever date is later.

(2) The responsible party for an applicable device clinical trial that is a pediatric postmarket surveillance of a device product and is not a clinical trial must submit clinical trial registration information, as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) or § 11.28(b), not later than December 26, 2007, or 21 calendar days after FDA approves the postmarket surveillance plan, whichever date is later.

§ 11.28 What constitutes clinical trial registration information?

(a) For each applicable clinical trial that must be registered with ClinicalTrials.gov, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party must submit the following information:

(1) For such applicable clinical trials that were initiated before January 18,

2017, the responsible party must submit the information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).

(2) For such applicable clinical trials that are initiated on or after January 18, 2017, the responsible party must submit the data elements listed below:

(i) Descriptive information:

(A) Brief Title;

(B) Official Title;

(C) Brief Summary;

(D) Primary Purpose;

(E) Study Design;

(F) Study Phase, for an applicable drug clinical trial;

(G) Study Type;

(H) Pediatric Postmarket Surveillance of a Device Product, for an applicable device clinical trial that is a Pediatric Postmarket Surveillance of a Device Product;

(I) Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study;

(J) Intervention Name(s), for each intervention studied;

(K) Other Intervention Name(s), for each intervention studied;

(L) Intervention Description, for each intervention studied;

(M) Intervention Type, for each intervention studied;

(N) Studies a U.S. FDA-regulated Device Product;

(O) Studies a U.S. FDA-regulated Drug Product;

(P) Device Product Not Approved or Cleared by U.S. FDA, if any studied intervention is a device product;

(Q) Post Prior to U.S. FDA Approval or Clearance, for an applicable device clinical trial that studies at least one device product not previously approved or cleared by the U.S. FDA;

(R) Product Manufactured in and Exported from the U.S., if the entry for U.S. Food and Drug Administration IND or IDE Number in § 11.28(a)(2)(iv)(C) indicates that there is no IND or IDE for the clinical trial, and the entry(ies) for Facility Information in § 11.28(a)(2)(iii)(C) include no facility locations in the United States or its territories;

(S) Study Start Date;

(T) Primary Completion Date;

(U) Study Completion Date;

(V) Enrollment;

(W) Primary Outcome Measure Information, for each primary outcome measure; and

(X) Secondary Outcome Measure Information, for each secondary outcome measure.

(ii) Recruitment information:

(A) Eligibility Criteria;

(B) Sex/Gender;

(C) Age Limits;

(D) Accepts Healthy Volunteers;

(E) Overall Recruitment Status;

(F) Why Study Stopped;

(G) Individual Site Status; and

(H) Availability of Expanded Access. If expanded access is available for an investigational drug product (including a biological product), an expanded access record must be submitted in accordance with § 11.28(c), unless an expanded access record was submitted previously in accordance with that provision.

(iii) Location and contact information:

(A) Name of the Sponsor;

(B) Responsible Party, by Official Title; and

(C) Facility Information.

(iv) Administrative data:

(A) Unique Protocol Identification Number;

(B) Secondary ID;

(C) U.S. Food and Drug Administration IND or IDE Number;

(D) Human Subjects Protection Review Board Status;

(E) Record Verification Date; and

(F) Responsible Party Contact Information.

(b) Pediatric postmarket surveillance of a device product that is not a clinical trial. For each pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party must submit the following information:

(1) For such applicable device clinical trials that were initiated before January 18, 2017, the responsible party must submit the information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).

(2) For such applicable device clinical trials that are initiated on or after January 18, 2017, the responsible party must submit the data elements listed below:

(i) Descriptive information:

(A) *Brief Title.* A short title of the pediatric postmarket surveillance of a device product in language intended for the lay public. If an acronym or abbreviation is used to publicly identify the surveillance, it must be provided.

(B) *Official Title.* The title of the pediatric postmarket surveillance of a device product, corresponding to the title of the protocol or the FDA-approved plan for conducting the surveillance

(C) *Brief Summary.* A short description of the pediatric postmarket surveillance of a device product, including a brief statement of the hypothesis or objective, written in language intended for the lay public, and a general description of the surveillance design, including relevant population information

(D) *Study Type.* The type of study being registered. In the case of a pediatric postmarket surveillance of a device product that is not a clinical trial, a study type of "observational" is required.

(E) *Pediatric Postmarket Surveillance of a Device Product.* For a study that includes an FDA-regulated device product as an intervention and is a pediatric postmarket surveillance of a device product

(F) *Primary Disease or Condition Being Studied, or the Focus of the Study.* The name(s) of the disease(s) or condition(s) being studied in the pediatric postmarket surveillance of a device product, or the focus of the surveillance study. Use, if available, appropriate descriptors fromNLM's MeSH-controlled vocabulary thesaurus or terms from another vocabulary, such as the SNOMED CT, that has been mapped to MeSH within the UMLS Metathesaurus.

(G) *Intervention Name(s).* A brief descriptive name used to refer to each intervention studied in the pediatric postmarket surveillance of a device product. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used.

(H) *Other Intervention Name(s).* Any other current and former name(s) or alias(es), different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention(s), including, but not limited to, past or present names such as brand name(s), or serial numbers

(I) *Intervention Description.* Details that can be made public about each intervention, other than the Intervention Name(s) and Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions studied in the same or another clinical trial or pediatric postmarket surveillance of a device product that is not a clinical trial

(J) *Intervention Type.* For each intervention studied in the pediatric postmarket surveillance of a device product, the general type of intervention

(K) *Study Start Date.* The date on which FDA approves the pediatric postmarket surveillance plan, as specified in 21 CFR 822.19(a).

(L) *Primary Completion Date.* The estimated or actual date on which the final report of the pediatric postmarket surveillance of a device product is expected to be submitted to FDA. Once the final report has been submitted, this is the actual date on which the final report is submitted to FDA.

(ii) Location and contact information:

(A) Name of the Sponsor.

(B) Responsible Party, by Official Title:

(*1*) If the responsible party is an entity, the official name of the entity; or

(*2*) If the responsible party is an individual, the official title and primary organizational affiliation of the individual.

(C) *Contact Information.* The name or official title, toll-free telephone number, and email address of a person to whom questions concerning the pediatric postmarket surveillance of a device product can be addressed.

(iii) Administrative data:

(A) *Unique Protocol Identification Number.* The unique identifier assigned to the pediatric postmarket surveillance of a device product by the sponsor, if any.

(B) *Secondary ID:* (*1*) Identifier(s) other than the organization's unique protocol identifier or NCT number that is assigned to the pediatric postmarket surveillance of a device product, if any, including any unique identifiers assigned by other publicly available clinical study registries. If the pediatric postmarket surveillance of a device product is funded in whole or in part by a U.S. Federal Government agency, the complete grant or contract number must be submitted as a Secondary ID.

(*2*) For each secondary ID listed, a description of the type of secondary ID.

(C) *Human Subjects Protection Review Board Status.* Information to indicate whether a pediatric postmarket surveillance of a device product has been reviewed and approved by a human subjects protection review board or whether such review is not required per applicable law (*e.g.,* 21 CFR part 56, 45 CFR part 46, or other applicable regulation). Human Subjects Protection Review Board Status must be listed as "approved" if at least one human subjects protection review board has approved the pediatric postmarket surveillance.

(D) *Record Verification Date.* The date on which the responsible party last verified the clinical trial information in the entire ClinicalTrials.gov record for the pediatric postmarket surveillance of a device product, even if no additional or updated information was submitted at that time

(E) *Responsible Party Contact Information.* Administrative information sufficient to identify and allow communication with the responsible party by telephone, email, and regular mail or delivery service. Responsible Party Contact Information includes the name, official title, organizational affiliation, physical address, mailing address, phone number, and email address of the individual who is the responsible party or of a designated employee of the organization that is the responsible party.

(c) *Expanded access record.* If expanded access is available, as specified in 21 CFR 312.315 (for an intermediate-size patient population) or 21 CFR 312.320 (under a treatment IND or treatment protocol), for an investigational drug product (including a biological product) studied in an applicable drug clinical trial, and the data elements set forth in paragraphs (c)(1) through (4) of this section have not been submitted in an expanded access record for that investigational product, the responsible party, if both the manufacturer of the investigational product and the sponsor of the applicable clinical trial, must submit the clinical trial information specified in paragraphs (c)(1) through (4) of this section to ClinicalTrials.gov in the form of an expanded access record. If expanded access is available only as specified in 21 CFR 312.310 (for individual patients, including for emergency use) for an investigational drug product (including a biological product) studied in an applicable drug clinical trial, and the data elements set forth in paragraphs (c)(1)(i), (iii), (iv), (vi), (ix), (x), (c)(2)(iv), (c)(3), (c)(4)(i), (iii),(iv), and (v) of this section have not been submitted in an expanded access record for that investigational product, the responsible party, if both the manufacturer of the investigational product and the sponsor of the applicable clinical trial, must submit the clinical trial information specified in those paragraphs to ClinicalTrials.gov in the form of an expanded access record.

(1) Descriptive information:

(i) *Brief Title.* A short title identifying the expanded access, written in language intended for the lay public. If an acronym or abbreviation is used publicly to identify the expanded access, it must be provided.

(ii) *Official Title.* The title, if any, of the expanded access program corresponding to the title that has been submitted to FDA for that program

(iii) *Brief Summary.* A short description of the availability of expanded access, including the procedure for requesting the investigational drug product (including a biological product).

(iv) *Study Type.* The nature of the investigation or investigational use for which clinical trial information is being submitted, *i.e.,* "expanded access".

(v) *Primary Disease or Condition.* The name(s) of the disease(s) or condition(s) for which expanded access to the investigational drug product (including a biological product) is available. Use, if available, appropriate descriptors from NLM's MeSH-controlled vocabulary thesaurus, or terms from another vocabulary, such as the SNOMED CT, that has been mapped to MeSH within the UMLS Metathesaurus.

(vi) *Intervention Name(s).* A brief descriptive name used to refer to the investigational drug product (including a biological product) that is available through expanded access. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used.

(vii) *Other Intervention Name(s).* Any other current and former name(s) or alias(es), different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention, including, but not limited to, past or present names such as brand name(s), or serial numbers.

(viii) *Intervention Description.* Details that can be made public about each intervention, other than the Intervention Name(s) or Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions that are available through expanded access or in clinical trials.

(ix) *Intervention Type.* For each investigational drug product (including a biological product) for which expanded access is available, the general type of intervention, *e.g.,* drug.

(x) *Expanded Access Type.* The type(s) of expanded access for which the investigational drug product (including a biological product) is available, as specified in § 11.10(b)(28).

(2) Recruitment information:

(i) *Eligibility Criteria.* A limited list of criteria for determining who is eligible to receive the investigational drug product (including a biological product) through expanded access, provided in terms of inclusion and exclusion criteria and suitable for assisting potential patients in identifying investigational drug products (including biological products) of interest for which expanded access is available.

(ii) *Sex/Gender.* The sex and gender (if applicable) of the patients for whom expanded access is available.

(iii) *Age Limits.* The minimum and maximum age of patients for whom expanded access is available, provided in relevant units of time.

(iv) *Expanded Access Status.* The status of availability of the investigational drug product (including a biological product) through expanded access.

(3) Contact information:

(i) *Name of the Sponsor.*

(ii) *Responsible Party, by Official Title.* The official name of the entity.

(iii) *Contact Information.* The name or official title, toll-free telephone number, and email address of a person to whom questions concerning expanded access can be addressed.

(4) Administrative data:

(i) *Unique Protocol Identification Number.* Any unique identifier assigned by the sponsor to refer to the availability of its investigational drug product (including a biological product) for expanded access use or to identify the expanded access record.

(ii) *Secondary ID:* (A) Any identifier(s) other than the Unique Protocol Identification Number or the NCT number that is assigned to the expanded access record, including any unique identifiers assigned by other publicly available clinical trial or expanded access registries.

(B) For each Secondary ID listed, a description of the type of Secondary ID.

(iii) *U.S. Food and Drug Administration IND Number.* An indication of whether there is an IND and, if so, each of the following elements:

(A) Name or abbreviation of the FDA center with whom the IND is filed (*i.e.,* CDER or CBER), if applicable;

(B) IND number (assigned by the FDA center) under which the investigational drug product (including a biological product) is being made available for expanded access, if applicable; and

(C) IND serial number. as defined in 21 CFR 312.23(e), if any, assigned to the expanded access.

(iv) *Record Verification Date.* The date on which the responsible party last verified the information in the expanded access record, even if no additional or updated information was submitted at that time.

(v) *Responsible Party Contact Information.* Administrative information sufficient to identify and allow communication with the responsible party entering the clinical trial information into the expanded access record by telephone, email, and regular mail or delivery service. Responsible Party Contact Information includes the name, official title, organizational affiliation, physical address, mailing address, phone number, and email address of the individual who is the responsible party or of a designated employee of the organization that is the responsible party.

§ 11.35 By when will the NIH Director post clinical trial registration information submitted under § 11.28?

(a) *Applicable drug clinical trial.* The Director will post publicly on *ClinicalTrials.gov* the clinical trial registration information, except for certain administrative data, for an applicable drug clinical trial not later than 30 calendar days after the responsible party has submitted such information, as specified in § 11.24.

(b) *Applicable device clinical trial.* (1) For an applicable device clinical trial of a device product that was previously approved or cleared, the Director will post publicly on *ClinicalTrials.gov* the clinical trial registration information, except for certain administrative data, as soon as practicable, but not later than 30 calendar days after clinical trial results information is required to be posted, as specified in § 11.52.

(2) For an applicable device clinical trial of a device product that has not been previously approved or cleared:

(i) The Director will post publicly on *ClinicalTrials.gov* the clinical trial registration information, except for certain administrative data, not earlier than the date of FDA approval or clearance of the device product and not later than 30 calendar days after the date of such approval or clearance, except as otherwise provided in paragraph (b)(2)(ii) of this section.

(ii) If, prior to the date of approval or clearance of the device product, the responsible party for an applicable clinical trial that is initiated on or after January 18, 2017, indicates to the Director, by submitting the Post Prior to U.S. FDA Approval or Clearance data element under § 11.28(a)(2)(i)(Q), that it is authorizing the Director to publicly post its clinical trial registration information, which would otherwise be subject to delayed posting as specified in paragraph (b)(2)(i) of this section, prior to the date of FDA approval or clearance of its device product, the Director will publicly post the registration information, except for certain administrative data, as soon as practicable.

Subpart C—Results Information Submission

§ 11.40 Who must submit clinical trial results information?

The responsible party for an applicable clinical trial specified in § 11.42 must submit clinical trial results information for that clinical trial.

§ 11.42 For which applicable clinical trials must clinical trial results information be submitted?

(a) *Applicable clinical trials for which the studied product is approved, licensed, or cleared by FDA.* Unless a waiver of the requirement to submit clinical trial results information is granted in accordance with § 11.54, clinical trial results information must be submitted for any applicable clinical trial for which the studied product is approved, licensed, or cleared by FDA for which submission of clinical trial registration information is required in accordance with the following:

(1) If the primary completion date is before January 18, 2017, the responsible party must submit the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)); or

(2) If the primary completion date is on or after January 18, 2017, the responsible party must submit the clinical trial results information specified in § 11.48.

(b) *Applicable clinical trials for which the studied product is not approved, licensed, or cleared by FDA.* Unless a waiver of the requirement to submit clinical trial results information is granted in accordance with § 11.54, clinical trial results information specified in § 11.48 must be submitted for any applicable clinical trial with a primary completion date on or after January 18, 2017 for which clinical trial registration information is required to be submitted and for which the studied product is not approved, licensed, or cleared by FDA.

§ 11.44 When must clinical trial results information be submitted for applicable clinical trials subject to § 11.42?

(a) *Standard submission deadline.* In general, for applicable clinical trials subject to § 11.42, clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)) or in § 11.48, as applicable, must be submitted no later than 1 year after the primary completion date of the applicable clinical trial.

(b) *Delayed submission of results information with certification if seeking approval, licensure, or clearance of a new use*—(1) *General requirements.* If, prior to the results information submission deadline specified under paragraph (a) of this section, the responsible party submits a certification that an applicable clinical trial involves an FDA-regulated drug product (including a biological product) or device product that previously has been approved, licensed, or cleared, for which the manufacturer is the sponsor of the applicable clinical trial and for which an application or premarket notification seeking approval, licensure, or clearance of the use being studied (which is not included in the labeling of the approved, licensed, or cleared drug product (including a biological product) or device product) has been filed or will be filed within 1 year with FDA, the deadline for submitting clinical trial results information, as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)) or § 11.48, as applicable, will be 30 calendar days after the earliest of the following events:

(i) FDA approves, licenses, or clears the drug product (including a biological product) or device product for the use studied in the applicable clinical trial;

(ii) FDA issues a letter that ends the regulatory review cycle for the application or submission but does not approve, license, or clear the drug product (including a biological product) or device product for the use studied in the applicable clinical trial; or

(iii) The application or premarket notification seeking approval, licensure, or clearance of the new use is withdrawn without resubmission for not less than 210 calendar days.

(2) *Two-year limitation.* Notwithstanding the deadlines specified in paragraph (b)(1) of this section, the responsible party must submit clinical trial results information specified in paragraph (b)(1) of this section not later than the date that is 2 years after the date that the certification was submitted, except to the extent that paragraph (d) of this section applies.

(3) *Additional requirements.* If a responsible party who is both the manufacturer of the drug product (including a biological product) or device product studied in an applicable clinical trial and the sponsor of the applicable clinical trial submits a certification in accordance with paragraph (b)(1) of this section, that responsible party must submit such a certification for each applicable clinical trial that meets the following criteria:

(i) The applicable clinical trial is required to be submitted in an application or premarket notification seeking approval, licensure, or clearance of a new use; and

(ii) The applicable clinical trial studies the same drug product (including a biological product) or device product for the same use as studied in the applicable clinical trial for which the initial certification was submitted.

(c) *Delayed submission of results with certification if seeking initial approval, licensure, or clearance.*—(1) *General requirements.* If, prior to the submission deadline specified under paragraph (a) of this section, a responsible party submits a certification that an applicable clinical trial studies an FDA-regulated drug product (including a biological product) or device product that was not approved, licensed, or cleared by FDA for any use before the primary completion date of the trial, and that the sponsor intends to continue with product development and is either seeking, or may at a future date seek, FDA approval, licensure, or clearance of the drug product (including a biological product) or device product under study, the deadline for submitting clinical trial results information, as specified in § 11.48, will be 30 calendar days after the earlier of the date on which:

(i) FDA approves, licenses, or clears the drug product (including a biological product) or device product for any use that is studied in the applicable clinical trial; or

(ii) The marketing application or premarket notification is withdrawn without resubmission for not less than 210 calendar days.

(2) *Two-year limitation.* Notwithstanding the deadlines established in paragraph (c)(1) of this section, the responsible party must submit clinical trial results information specified in paragraph (c)(1) of this section not later than 2 years after the date on which the certification was submitted, except to the extent that paragraph (d) of this section applies.

(d) *Submitting partial results information.* (1) If clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)) or § 11.48, as applicable, has not been collected for a secondary outcome measure(s) or additional adverse event information by the primary completion date, the responsible party must submit the remaining required clinical trial results information for secondary outcome measure(s) or additional adverse event information for that clinical trial by the following deadlines:

(i) For secondary outcome measure(s), by the later of:

(A) One year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for that secondary outcome measure, whether the clinical trial was concluded according to the pre-specified protocol or was terminated; or

(B) If a certification to delay results information submission has been submitted under paragraph (b) or (c) of this section, the date on which results information for the primary outcome measures is due pursuant to paragraph (b) or (c) of this section.

(ii) For additional adverse event information, by the later of:

(A) One year after the date of data collection for additional adverse event information, whether the clinical trial was concluded according to the pre-specified protocol or was terminated; or

(B) If a certification to delay results information submission has been submitted under paragraph (b) or (c) of this section, the date on which results information for the primary outcome measures is due pursuant to paragraph (b) or (c) of this section.

(2) Except, if clinical trial results information was submitted for the primary outcome measure(s) prior to the effective date of these regulations but data collection for all of the secondary outcome measure(s) or additional adverse event information is not completed until on or after January 18, 2017, clinical trial results information for all primary and secondary outcome measures and adverse event information for the clinical trial must be submitted as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)).

(3) For each submission of partial results information for a clinical trial, as specified in paragraph (d)(1) of this section:

(i) If any amendments were made to the protocol and/or statistical analysis plan as described in § 11.48(a)(5) since the previous submission of partial results information, the responsible party must submit a copy of the revised protocol and/or statistical analysis plan; and

(ii) If information about certain agreements as described in § 11.48(a)(6)(ii) has changed since the previous submission of partial results information, the responsible party must submit information to reflect the new status of certain agreements between the principal investigator and the sponsor.

(e) *Extensions for good cause.* (1) A responsible party may request an extension of the deadline for submitting clinical trial results information subject to paragraphs (e)(1)(i) and (ii) of this section or section 402(j)(3)(E)(vi) of the Public Health Service Act (42 U.S.C. 282(j)(3)(E)(vi)), as applicable, and may request more than one extension for the same applicable clinical trial.

(i) The responsible party must submit a request for an extension to *ClinicalTrials.gov* prior to the date on which clinical trial results information would otherwise be due in accordance with paragraph (a), (b), (c), (d), (e), or (f) of this section.

(ii) A request for an extension must contain the following:

(A) Description of the reason(s) why clinical trial results information cannot be provided according to the deadline, with sufficient detail to allow for the evaluation of the request; and

(B) Estimate of the date on which the clinical trial results information will be submitted.

(2) *Decision and submission deadline.* The Director will provide a response electronically to the responsible party indicating whether the requested extension demonstrates good cause and has been granted.

(i) If the extension request is granted, the responsible party must submit clinical trial results information not later than the date of the deadline specified in the electronic response.

(ii) If the extension request is denied, the responsible party must either appeal in accordance with paragraph (e)(3) of this section or submit clinical trial results information specified in § 11.48 by the later of the submission deadline specified in paragraph (a), (b), (c), (d), (e), or (f) of this section, as applicable, or 30 calendar days after the date on which the electronic notice of the denial is sent to the responsible party.

(3) *Appealing a denied extension request.* (i) A responsible party who seeks to appeal a denied extension request or the deadline specified in a granted extension must submit an appeal to the Director in the format specified at *https://prsinfo.clinicaltrials.gov/* not later than 30 calendar days after the date on which the electronic notification of the granting or denial of the request is sent to the responsible party.

(ii) An appeal must contain an explanation of the reason(s) why the initial decision to deny the extension request or to grant the extension request with a shorter deadline than requested should be overturned or revised, with sufficient detail to allow for the evaluation of the appeal.

(iii) The Director will provide an electronic notification to the responsible party indicating whether the requested extension has been granted upon appeal.

(iv) If the Director grants the extension request upon appeal, the responsible party must submit clinical trial results information not later than the deadline specified in the electronic notification specified in paragraph (e)(3)(iii) of this section.

(v) If the Director denies the appeal of a denied extension request, the responsible party must submit clinical trial results information by the later of the deadline specified in paragraph (a), (b), (c), (d), (e), or (f) of this section, or 30 calendar days after the electronic notification of the denial of the appeal, specified in paragraph (e)(3)(iii) of this section, is sent to the responsible party.

(vi) If the Director denies an appeal of a denied deadline specified in a granted extension request, the responsible party must submit clinical trial results information by the later of the deadline specified in the notification granting the extension request, specified in paragraph (e)(2)(i) of this section, or 30 calendar days after the electronic notification denying the appeal, specified in paragraph (e)(3)(iii) of this section, is sent to the responsible party.

(f) *Pediatric postmarket surveillance of a device product that is not a clinical trial.* For each pediatric postmarket surveillance of a device product that is not a clinical trial as defined in this part, the responsible party must submit clinical trial results information as specified in § 11.48(b) or section 402(j)(C)(3) of the Public Health Service Act (42 U.S.C. 282(j)(C)(3)), as applicable, not later than 30 calendar days after the date on which the final report of the approved pediatric postmarket surveillance of a device product, as specified in 21 CFR 822.38, is submitted to FDA.

§ 11.48 What constitutes clinical trial results information?

(a) For each applicable clinical trial, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, for which clinical trial results information must be submitted under § 11.42, the responsible party must provide the following:

(1) *Participant flow.* Information for completing a table documenting the progress of human subjects through a clinical trial, by arm, including the number who started and completed the clinical trial. This information must include the following elements:

(i) *Participant Flow Arm Information.* A brief description of each arm used for describing the flow of human subjects through the clinical trial, including a descriptive title used to identify each arm;

(ii) *Pre-assignment Information.* A description of significant events in the clinical trial that occur after enrollment and prior to assignment of human subjects to an arm, if any; and

(iii) *Participant Data.* The number of human subjects that started and completed the clinical trial, by arm. If assignment is based on a unit other than participants, also include a description of the unit of assignment and the number of units that started and completed the clinical trial, by arm.

(2) *Demographic and baseline characteristics.* Information for completing a table of demographic and baseline measures and data collected by arm or comparison group and for the entire population of human subjects who participated in the clinical trial. This information must include the following elements:

(i) *Baseline Characteristics Arm/Group Information.* A brief description of each arm or comparison group used for describing the demographic and baseline characteristics of the human subjects in the clinical trial, including a descriptive title used to identify each arm or comparison group.

(ii) *Baseline Analysis Population Information*—(A) *Overall Number of Baseline Participants.* The total number of human subjects for whom baseline characteristics were measured, by arm or comparison group and overall.

(B) *Overall Number of Units Analyzed.* If the analysis is based on a unit other than participants, a description of the unit of analysis and the number of units for which baseline measures were measured and analyzed, by arm or comparison group and overall.

(C) *Analysis Population Description.* If the Overall Number of Baseline Participants (or units) differs from the number of human subjects (or units) assigned to the arm or comparison group and overall, a brief description of the reason(s) for the difference.

(iii) *Baseline Measure Information.* A description of each baseline or demographic characteristic measured in the clinical trial, including age, sex/gender, race, ethnicity (if collected under the protocol), and any other measure(s) that were assessed at baseline and are used in the analysis of the primary outcome measure(s) in accordance with § 11.48(a)(3). The description of each measure must include the following elements:

(A) Name and description of the measure, including any categories that are used to submit Baseline Measure Data.

(B) *Measure Type and Measure of Dispersion:* For each baseline measure submitted, an indication of the type of data to be submitted and the associated measure of dispersion.

(C) *Unit of Measure.* For each baseline measure for which data are collected, the unit of measure.

(iv) *Baseline Measure Data.* The value(s) for each submitted baseline measure, by arm or comparison group and for the entire population of human subjects for whom baseline characteristics were measured.

(v) Number of baseline participants (and units), by arm or comparison group and overall, if different from the Overall Number of Baseline Participants or Overall Number of Units Analyzed in § 11.48(a)(2)(ii)(A) and (B), respectively.

(3) *Outcomes and statistical analyses.* Information for completing a table of data for each primary and secondary outcome measure by arm or comparison group, including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any. This information must include the following elements:

(i) *Outcome Measure Arm/Group Information.* A brief description of each arm or comparison group used for submitting an outcome measure for the clinical trial, including a descriptive title to identify each arm or comparison group.

(ii) *Analysis Population Information*—(A) *Number of Participants Analyzed.* The number of human subjects for whom an outcome was measured and analyzed, by arm or comparison group.

(B) *Number of Units Analyzed.* If the analysis is based on a unit other than participants, a description of the unit of analysis and the number of units for which an outcome was measured and analyzed, by arm or comparison group.

(C) *Analysis Population Description.* If the Number of Participants Analyzed or Number of Units Analyzed differs from the number of human subjects or units assigned to the arm or comparison group, a brief description of the reason(s) for the difference.

(iii) *Outcome Measure Information.* A description of each outcome measure, to include the following elements:

(A) Name of the specific outcome measure, including the titles of any categories in which Outcome Measure Data in § 11.48(a)(3)(iv) are aggregated.

(B) Description of the metric used to characterize the specific outcome measure.

(C) Time point(s) at which the measurement was assessed for the specific metric.

(D) *Outcome Measure Type.* The type of outcome measure, whether primary, secondary, other pre-specified, or post-hoc.

(E) *Measure Type and Measure of Dispersion or Precision.* For each outcome measure for which data are collected, the type of data submitted and the measure of dispersion or precision.

(F) *Unit of Measure.* For each outcome measure for which data are collected, the unit of measure.

(iv) *Outcome Measure Data.* The measurement value(s) for each outcome measure for which data are collected, by arm or comparison group and by category (if specified).

(v) *Statistical Analyses.* Result(s) of scientifically appropriate tests of the statistical significance of the primary and secondary outcome measures, if any.

(A) A statistical analysis is required to be submitted if it is:

(*1*) Pre-specified in the protocol and/or statistical analysis plan and was performed on the outcome measure data,

(*2*) Made public by the sponsor or responsible party prior to the date on which clinical trial results information is submitted for the primary outcome measures(s) studied in the clinical trial to which the statistical analysis applies, or

(*3*) Conducted on a primary outcome measure in response to a request made by FDA prior to the date on which clinical trial results information is submitted for the primary outcome measure(s) studied in the clinical trial to which the statistical analysis applies.

(B) Information for each statistical analysis specified in paragraph (a)(3)(v)(A) of this section must include the following elements:

(*1*) *Statistical Analysis Overview:* Identification of the arms or comparison groups compared in the statistical analysis; the type of statistical test conducted; and, for a non-inferiority or equivalence test, a description of the analysis that includes, at minimum, the power calculation and non-inferiority or equivalence margin.

(*2*) One of the following, as applicable:

(*i*) *Statistical Test of Hypothesis:* The p-value and the procedure used for the statistical analysis; or

(*ii*) *Method of Estimation:* The estimation parameter, estimated value, and confidence interval (if calculated).

(4) *Adverse event information.* (i) Information to describe the methods for collecting adverse events during an applicable clinical trial:

(A) *Time Frame.* The specific period of time over which adverse event information was collected and for which information is submitted in paragraph (a)(4)(iii) of this section.

(B) *Adverse Event Reporting Description.* If the adverse event information collected in the clinical trial is collected based on a different definition of adverse event and/or serious adverse event than defined in this part, a brief description of how those definitions differ.

(C) *Collection Approach.* The type of approach taken to collect adverse event information, whether systematic or non-systematic.

(ii) Information for completing three tables summarizing anticipated and unanticipated adverse events collected during an applicable clinical trial:

(A) Table of all serious adverse events grouped by organ system, with the number and frequency of each event by arm or comparison group;

(B) Table of all adverse events, other than serious adverse events, that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with the number and frequency of each event by arm or comparison group; and

(C) Table of all-cause mortality, with the number and frequency of deaths due to any cause by arm or comparison group.

(iii) Information for each table specified in paragraph (a)(4)(ii) of this section must include the following elements, unless otherwise specified:

(A) *Adverse Event Arm/Group Information.* A brief description of each arm or comparison group used for submitting adverse event information from the clinical trial, including a descriptive title used to identify each arm or comparison group.

(B) *Total Number Affected.* The overall number of human subjects affected, by arm or comparison group, by:

(*1*) Serious adverse event(s);

(*2*) Adverse event(s) other than serious adverse events that exceed a frequency of 5 percent within any arm of the clinical trial; and

(*3*) Deaths due to any cause.

(C) *Total Number at Risk.* The overall number of human subjects included in the assessment, by arm or comparison group, for:

(*1*) Serious adverse events;

(*2*) Adverse event(s) other than serious adverse events that exceed a frequency of 5 percent within any arm of the clinical trial; or

(*3*) Deaths due to any cause.

(D) *Adverse Event Information.* For the two tables described in paragraphs (a)(4)(ii)(A) and (B) of this section, a description of each type of serious adverse event and other adverse event that is not a serious adverse event and exceeds a frequency of 5 percent within any arm of the clinical trial, consisting of the following attributes:

(*1*) Descriptive term for the adverse event; and

(*2*) Organ system associated with the adverse event.

(E) *Adverse Event Data.* For the two tables described in paragraphs (a)(4)(ii)(A) and (B) of this section and for each adverse event listed in accordance with paragraph (a)(4)(iii)(D) of this section:

(*1*) Number of human subjects affected by such adverse event.

(*2*) Number of human subjects at risk for such adverse event.

(5) *Protocol and statistical analysis plan.* A copy of the protocol and the statistical analysis plan (if not included in the protocol), including all amendments that have been approved by a human subjects protection review board (if applicable) before the time of submission under this subsection and that apply to all clinical trial Facility Locations. The responsible party must include the Official Title (as defined in § 11.10(b)(2)), NCT number (as defined in § 11.10(a)) (if available), and date of the protocol and the statistical analysis plan on the cover page of each document. The responsible party may redact names, addresses, and other personally identifiable information, as well as any trade secret and/or confidential commercial information (as those terms are defined in the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905)) contained in the protocol or statistical analysis plan prior to submission, unless such information is otherwise required to be submitted under this part. The protocol and statistical analysis plan must be submitted in a common electronic document format specified at *https://prsinfo.clinicaltrials.gov.*

(6) *Administrative information*—(i) *Results Point of Contact.* Point of contact for scientific information about the clinical trial results information, including the following:

(A) Name or official title of the point of contact

(B) Name of the affiliated organization, and

(C) Telephone number and email address of the point of contact.

(ii) Certain Agreements. An indication of whether the principal investigator is an employee of the sponsor and, if not, whether there exists any agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of human subjects participating in the clinical trial) between the sponsor or its agent and the principal investigator that restricts in any manner the ability of the principal investigator, after the primary completion date of the clinical trial, to discuss the results of the clinical trial at a scientific meeting or any other public or private forum or to publish in a scientific or academic journal information concerning the results of the clinical trial

(7) *Additional clinical trial results information for applicable device clinical trials of unapproved or uncleared device products.* (i) For an applicable device clinical trial of an unapproved or uncleared device product and for which clinical trial registration information has not been posted publicly on Clinical Trials.gov by the Director in accordance with § 11.35(b)(2)(i), the responsible party must provide the following data elements, as the data elements are defined in § 11.10(b): Brief Title; Official Title; Brief Summary; Primary Purpose; Study Design; Study Type; Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study; Intervention Name(s); Other Intervention Name(s); Intervention Description; Intervention Type; Device Product Not Approved or Cleared by U.S. FDA, if any studied intervention is a device product; Study Start Date; Primary Completion Date; Study Completion Date, Enrollment; Primary Outcome Measure Information; Secondary Outcome Measure Information; Eligibility Criteria; Sex/Gender; Age Limits; Accepts Healthy Volunteers; Overall Recruitment Status; Why Study Stopped; Name of the Sponsor; Responsible Party, by Official Title; Facility Name and Facility Location, for each participating facility in a clinical trial; Unique Protocol Identification Number; Secondary ID; Human Subjects Protection Review Board Status; and Record Verification Date.

(ii) The responsible party shall submit all the results information specified in paragraph (a)(7)(i) and must submit an affirmation that any information previously submitted to *ClinicalTrials.gov* for the data elements listed in paragraph (a)(7)(i) of this section have been updated in accordance with § 11.64(a) and are to be included as clinical trial results information.

(b) *Pediatric postmarket surveillance of a device product that is not a clinical trial.* For each pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party must submit a copy of any final report that is submitted to FDA as specified in 21 CFR 822.38. The responsible party may redact names, addresses, and other personally identifiable information or commercial confidential information contained in the final report prior to submission to NIH, unless such information is otherwise required to be submitted under this part. The final report must be in a common electronic document format specified at *https://prsinfo.clinicaltrials.gov.*

§ 11.52 By when will the NIH Director post submitted clinical trial results information?

Except for clinical trial results information submitted under section 402(j)(4)(A) of the PHS Act and § 11.60, the Director will post publicly clinical trial results information on *ClinicalTrials.gov* not later than 30 calendar days after the date of submission.

§ 11.54 What are the procedures for requesting and obtaining a waiver of the requirements for clinical trial results information submission?

(a) *Waiver request.* (1) A responsible party for an applicable clinical trial with a primary completion date on or after January 18, 2017 may request a waiver from any applicable requirement(s) of this subpart C by submitting a waiver request in the format specified at *https://prsinfo.clinicaltrials.gov/* to the Secretary or delegate prior to the deadline specified in § 11.44(a) for submitting clinical trial results information.

(2) The waiver request must contain:

(i) The NCT number, Brief Title, and Name of the Sponsor of the applicable clinical trial for which the waiver is requested;

(ii) The specific requirement(s) of this subpart C for which the waiver is requested; and

(iii) A description of the extraordinary circumstances that the responsible party believes justify the waiver and an explanation of why granting the request would be consistent with the protection of public health or in the interest of national security.

(3) The responsible party will not be required to comply with the specified requirements of this subpart for which a waiver is granted.

(4) The responsible party must comply with any requirements of this subpart for which a waiver is not granted or must submit an appeal as set forth in paragraph (b) of this section. The deadline for submitting any required clinical trial results information will be the later of the original submission deadline or 30 calendar days after the notification of the denial is sent to the responsible party.

(b) *Appealing a denied waiver request.* (1) A responsible party for an applicable clinical trial with a primary completion date on or after January 18, 2017 may appeal a denied waiver request by submitting an appeal to the Secretary or delegate in the format specified at *https://prsinfo.clinicaltrials.gov/* not later than 30 calendar days after the date on which the electronic notification of the denial in paragraph (a)(4) of this section denying the request is sent to the responsible party.

(2) The responsible party is not required to comply with any requirements of this subpart for which a waiver is granted upon appeal.

(3) The responsible party must submit clinical trial results information to comply with any requirements of this subpart that are not waived upon appeal by the later of the original submission deadline or 30 calendar days after the notice of the denial upon appeal is sent to the responsible party.

(c) If a waiver is granted under paragraph (a) or (b) of this section:

(1) The Director will include a notation in the clinical trial record that specified elements of the requirements of this part have been waived.

(2) The Secretary will notify, in writing, the appropriate committees of Congress and provide an explanation for why the waiver was granted, not later than 30 calendar days after any waiver is granted.

(d) A responsible party for an applicable clinical trial with a primary completion date before January 18, 2017 may request a waiver from any applicable requirement(s) for clinical trial results information submission by submitting a waiver request, as specified in section 402(j)(3)(H) of the Public Health Service Act (42 U.S.C. 282(j)(3)(H)).

Subpart D—Additional Submissions of Clinical Trial Information

§ 11.60 What requirements apply to the voluntary submission of clinical trial information for clinical trials of FDA-regulated drug products (including biological products) and device products?

(a) If a responsible party voluntarily submits clinical trial information for a clinical trial described in paragraph (a)(1) of this section, the responsible party must meet the conditions specified in paragraph (a)(2) of this section.

(1) The requirements of paragraph (a) of this section apply to a clinical trial that was initiated before January 18, 2017 and has a primary completion date before January 18, 2017, and that is either:

(i) A clinical trial of an FDA-regulated drug product (including a biological product) or device product that is not an applicable clinical trial, or

(ii) An applicable clinical trial that is not otherwise required to submit clinical trial registration information.

(2) If the responsible party for a clinical trial described in paragraph (a)(1) of this section voluntarily submits clinical trial registration information and/or clinical trial results information, the responsible party must comply with the following requirements:

(i) The responsible party must submit the information in paragraphs (b)(2)(i)(A), (B), or (C) of this section for the clinical trial being submitted voluntarily.

(A) If the responsible party voluntarily registers a clinical trial, the responsible party must submit clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).

(B) If the responsible party voluntarily submits clinical trial results information for a clinical trial for which the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) has not been submitted, the responsible party must submit the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)).

(C) If the responsible party both voluntarily submits clinical trial registration information and voluntarily submits clinical trial results information, the responsible party must submit both clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) and clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)).

(ii) If, on or after September 27, 2007, a manufacturer submits an application or premarket notification to FDA for approval, licensure, or clearance of a drug product (including a biological product) or device product under sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) for the use studied in the clinical trial submitted under paragraph (a)(1) of this section, the responsible party specified in paragraph (a)(1) of this section must also submit the information specified in paragraph (a)(2)(iii) of this section by the deadline specified in paragraph (a)(2)(iv)(B) of this section for any applicable clinical trial that has not been submitted to *ClinicalTrials.gov* and that meets the following criteria:

(A) The applicable clinical trial is required to be submitted to FDA under sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) in an application or premarket notification for approval, licensure, or clearance to market the drug product (including a biological product) or device product for the use studied in the clinical trial specified in paragraph (a)(1) of this section; and

(B) The manufacturer of the drug product (including a biological product) or device product studied in the applicable clinical trial is also the responsible party for the clinical trial specified in paragraph (a)(1) of this section.

(iii) Information to be submitted for clinical trials described in paragraph (a)(2)(ii) of this section:

(A) If the clinical trial information voluntarily submitted for a clinical trial described in paragraph (a)(1) of this section consists only of the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)), the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist, at minimum, of the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).

(B) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (a)(1) of this section consists of the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)), the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist of the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)).

(C) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (a)(1) of this section consists of both the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) and the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)), the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist of both the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) and the clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)).

(iv) Submission deadlines:

(A) Secondary outcome measure(s) and adverse event information for voluntarily submitted clinical trials, under paragraph (a) of this section:

(1) If data collection for secondary outcome measure(s) for a voluntarily submitted clinical trial under paragraph (a) of this section is not completed by the primary completion date of the voluntarily submitted clinical trial, clinical trial results information for the secondary outcome measure(s) required in section 402(j)(3)(C) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C)) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date on which the final subject was examined or received an intervention for the purposes of final collection of data for the secondary outcome(s), whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(2) If data collection for adverse event information continues after the primary completion date of the voluntarily submitted clinical trial, any adverse event information collected after the primary completion date and subject to the submission requirements in section 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(I)) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date of final collection of data for adverse event information, whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(B) The clinical trial information specified in paragraph (a)(2)(iii) of this section must be submitted not later than the later of the date on which the application or premarket notification to FDA for approval, licensure, or clearance to market a drug product (including a biological product) or device product under section 351 of the Public Health Service Act (42 U.S.C. 262) or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) for the use studied in the clinical trial specified under paragraph (a)(1) of this section is submitted to FDA or the date on which the clinical trial information specified in paragraph (a)(2)(i) of this section for the clinical trial specified under paragraph (a)(1) of this section is submitted to *ClinicalTrials.gov.*

(b) If a responsible party voluntarily submits clinical trial information for a clinical trial described in paragraph (b)(1) of this section, the responsible party must meet the conditions specified in paragraph (b)(2) of this section.

(1) The requirements of paragraph (b) of this section apply to a clinical trial that was initiated before January 18, 2017 and has a primary completion date on or after January 18, 2017, and that is either:

(i) A clinical trial of an FDA-regulated drug product (including a biological product) or device product that is not an applicable clinical trial; or

(ii) An applicable clinical trial that is not otherwise required to submit clinical trial registration information.

(2) If the responsible party for a clinical trial described in paragraph (b)(1) of this section voluntarily submits clinical trial registration information and/or clinical trial results information, the responsible party must comply with the following requirements:

(i) The responsible party must submit the information in paragraph (b)(2)(i)(A), (B), or (C) of this section for the clinical trial being submitted voluntarily.

(A) If the responsible party voluntarily registers a clinical trial, the responsible party must submit clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).

(B) If the responsible party voluntarily submits clinical trial results information for a clinical trial for which the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) has not been submitted, the responsible party must submit the data elements specified in § 11.48, as well as the data elements listed below, as those data elements are defined in § 11.10(b) and apply to the clinical trial and the intervention(s) studied: Brief Title; Official Title; Brief Summary; Primary Purpose; Study Design; Study Phase, for a clinical trial of a drug product (including a biological product); Study Type; Pediatric Postmarket Surveillance of a Device Product; Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study; Intervention Name(s), for each intervention studied; Other Intervention Name(s), for each intervention studied; Intervention Description, for each intervention studied; Intervention Type, for each intervention studied; Device Product Not Approved or Cleared by U.S. FDA, if any studied intervention is a device product; Product Manufactured in and Exported from the U.S.; Studies a U.S. FDA-regulated Device Product; Studies a U.S. FDA-regulated Drug Product; Study Start Date; Primary Completion Date; Study Completion Date; Enrollment; Eligibility Criteria; Sex/Gender; Age Limits; Accepts Healthy Volunteers; Overall Recruitment Status; Why Study Stopped; Availability of Expanded Access, if any studied intervention is an investigational drug product (including a biological product); Name of the Sponsor; Responsible Party, by Official Title; Facility Information, for each participating facility; Unique Protocol Identification Number; Secondary ID; U.S. Food and Drug Administration IND or IDE Number; Human Subjects Protection Review Board Status; Record Verification Date; and Responsible Party Contact Information.

(C) If the responsible party both voluntarily submits clinical trial registration information and voluntarily submits clinical trial results information, the responsible party must submit both the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) and the clinical trial results information specified in § 11.48.

(ii) If, on or after September 27, 2007, a manufacturer submits an application or premarket notification to FDA for approval, licensure, or clearance of a drug product (including a biological product) or device product under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) for the use studied in the clinical trial submitted under paragraph (b)(1) of this section, the responsible party specified in paragraph (b)(1) of this section must also submit the information specified in paragraph (b)(2)(iii) of this section by the deadline specified in paragraph (b)(2)(iv)(B) of this section for any applicable clinical trial that has not been submitted to *ClinicalTrials.gov* and that meets the following criteria:

(A) The applicable clinical trial is required to be submitted to FDA under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) in an application or premarket notification for approval, licensure, or clearance to market the drug product (including a biological product) or device product for the use studied in the clinical trial specified in paragraph (b)(1) of this section; and

(B) The manufacturer of the drug product (including a biological product) or device product studied in the applicable clinical trial is also the responsible party for the clinical trial specified in paragraph (b)(1) of this section.

(iii) Information to be submitted for clinical trials described in paragraph (b)(2)(ii) of this section:

(A) If the clinical trial information voluntarily submitted for a clinical trial described in paragraph (b)(1) of this section consists only of the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)), the information to be submitted in accordance with paragraph (b)(2)(ii) of this section must consist, at minimum, of the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)).

(B) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (b)(1) of this section consists of the clinical trial results information specified in § 11.60(b)(2)(i)(B), the information to be submitted in accordance with paragraph (b)(2)(ii) of this section must consist of the clinical trial results information specified in § 11.60(b)(2)(i)(B).

(C) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (b)(1) of this section consists of both the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) and the clinical trial results information specified in § 11.48, the information to be submitted in accordance with paragraph (b)(2)(ii) of this section must consist of both the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) and the clinical trial results information specified in § 11.48.

(iv) Submission deadlines:

(A) Secondary outcome measure(s) and adverse event information for voluntarily submitted clinical trials, under paragraph (b) of this section:

(*1*) If data collection for secondary outcome measure(s) for a voluntarily submitted clinical trial under paragraph (b) of this section is not completed by the primary completion date of the voluntarily submitted clinical trial, clinical trial results information for the secondary outcome measure(s) required in § 11.48(a)(3) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date on which the final subject was examined or received an intervention for the purposes of final collection of data for the secondary outcome(s), whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(*2*) If data collection for adverse event information continues after the primary completion date of the voluntarily submitted clinical trial, any adverse event information collected after the primary completion date and subject to the submission requirements in § 11.48(a)(4) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date of final collection of data for adverse event information, whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(B) The clinical trial information specified in paragraph (b)(2)(iii) of this section must be submitted not later than the later of the date on which the application or premarket notification to FDA for approval, licensure, or clearance to market a drug product (including a biological product) or device product under section 351 of the Public Health Service Act (42 U.S.C. 262) or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) for the use studied in the clinical trial specified under paragraph (b)(1) of this section is submitted to FDA or the date on which the clinical trial information specified in paragraph (b)(2)(i) of this section for the clinical trial specified under paragraph (b)(1) of this section is submitted to *ClinicalTrials.gov.*

(c) If a responsible party voluntarily submits clinical trial information for a clinical trial described in paragraph (c)(1) of this section, the responsible party must meet the conditions specified in paragraph (c)(2) of this section.

(1) The requirements of paragraph (c) of this section apply to a clinical trial that was initiated on or after January 18, 2017 and has a primary completion date on or after January 18, 2017, and that is either:

(i) A clinical trial of an FDA-regulated drug product (including a biological product) or device product that is not an applicable clinical trial; or

(ii) An applicable clinical trial that is not otherwise required to submit clinical trial registration information.

(2) If the responsible party for a clinical trial described in paragraph (c)(1) of this section voluntarily submits clinical trial registration information and/or clinical trial results information, the responsible party must comply with the following requirements:

(i) The responsible party must submit the information in paragraph (c)(2)(i)(A), (B), or (C) of this section for the clinical trial being submitted voluntarily.

(A) If the responsible party voluntarily registers a clinical trial, the responsible party must submit the clinical trial registration information specified in § 11.28(a).

(B) If the responsible party voluntarily submits clinical trial results information for a clinical trial for which the clinical trial registration information specified in § 11.28(a) has not been submitted, the responsible party must submit the data elements specified in paragraph (b)(2)(i)(B) of this section.

(C) If the responsible party both voluntarily submits clinical trial registration information and voluntarily submits clinical trial results information, the responsible party must submit both the clinical trial registration information specified in § 11.28(a) and the clinical trial results information specified in § 11.48.

(ii) If, on or after September 27, 2007, a manufacturer submits an application or premarket notification to FDA for approval, licensure, or clearance of a drug product (including a biological product) or device product under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) for the use studied in the clinical trial submitted under paragraph (c)(1) of this section, the responsible party specified in paragraph (c)(1) of this section must also submit the information specified in paragraph (c)(2)(iii) of this section by the deadline specified in paragraph (c)(2)(iv)(B) of this section for any applicable clinical trial that has not been submitted to *ClinicalTrials.gov* and that meets the following criteria:

(A) The applicable clinical trial is required to be submitted to FDA under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) or section 351 of the Public Health Service Act (42 U.S.C. 262) in an application or premarket notification for approval, licensure, or clearance to market the drug product (including a biological product) or device product for the use studied in the clinical trial specified in paragraph (c)(1) of this section; and

(B) The manufacturer of the drug product (including a biological product) or device product studied in the applicable clinical trial is also the responsible party for the clinical trial specified in paragraph (c)(1) of this section.

(iii) Information to be submitted for clinical trials described in paragraph (c)(2)(ii) of this section:

(A) If the clinical trial information voluntarily submitted for a clinical trial described in paragraph (c)(1) of this section consists only of the clinical trial registration information specified in § 11.28(a), the information to be submitted in accordance with paragraph (c)(2)(ii) of this section must consist, at minimum, of the clinical trial registration information specified in § 11.28(a).

(B) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (c)(1) of this section consists of the clinical trial results information specified in § 11.60(c)(2)(i)(B), the information to be submitted in accordance with paragraph (c)(2)(ii) of this section must consist of the clinical trial results information specified in § 11.60(c)(2)(i)(B).

(C) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (c)(1) of this section consists of both the clinical trial registration information specified in § 11.28(a) and the clinical trial results information specified in § 11.48, the information to be submitted in accordance with paragraph (c)(2)(ii) of this section must consist of both the clinical trial registration information specified in § 11.28(a) and the clinical trial results information specified in § 11.48.

(iv) Submission deadlines:

(A) Secondary outcome measure(s) and adverse event information for voluntarily-submitted clinical trials, under paragraph (c) of this section:

(*1*) If data collection for secondary outcome measure(s) for a voluntarily submitted clinical trial under paragraph (c) of this section is not completed by the primary completion date of the voluntarily submitted clinical trial, clinical trial results information for the secondary outcome measure(s) required in § 11.48(a)(3) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date on which the final subject was examined or received an intervention for the purposes of final collection of data for the secondary outcome(s), whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(*2*) If data collection for adverse event information continues after the primary completion date of the voluntarily submitted clinical trial, any adverse event information collected after the primary completion date and subject to the submission requirements in § 11.48(a)(4) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date of final collection of data for adverse events information, whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(B) The clinical trial information specified in paragraph (c)(2)(iii) of this section must be submitted not later than the later of the date on which the application or premarket notification to FDA for approval, licensure, or clearance to market a drug product (including a biological product) or device product under section 351 of the Public Health Service Act (42 U.S.C. 262) or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360e, 360j(m)) for the use studied in the clinical trial specified under paragraph (c)(1) of this section is submitted to FDA or the date on which the clinical trial information specified in paragraph (c)(2)(i) of this section for the clinical trial specified under paragraph (c)(1) of this section is submitted to *ClinicalTrials.gov.*

(v) All submissions of clinical trial information under paragraph (c) of this section are subject to the applicable update and corrections requirements specified in § 11.64.

(d) Statement to accompany applicable clinical trials submitted under paragraphs (a), (b), and (c) of this section. Each applicable clinical trial for which clinical trial information is submitted under paragraphs (a), (b), and (c) of this section and posted on *ClinicalTrials.gov* will include the statement "This clinical trial information was submitted voluntarily under the applicable law and, therefore, certain submission deadlines may not apply. (That is, clinical trial information for this applicable clinical trial was submitted under section 402(j)(4)(A) of the Public Health Service Act and 42 CFR 11.60 and is not subject to the deadlines established by sections 402(j)(2) and (3) of the Public Health Service Act or 42 CFR 11.24 and 11.44.)"

§ 11.62 What requirements apply to applicable clinical trials for which submission of clinical trial information has been determined by the Director to be necessary to protect the public health?

(a) A responsible party who receives notification that the Director has determined that posting of clinical trial information for an applicable clinical trial described in paragraph (b) of this section is necessary to protect the public health must submit clinical trial information as specified in paragraph (c) of this section.

(b) An applicable clinical trial subject to this section must be either:

(1) An applicable clinical trial of an approved, licensed, or cleared drug product (including a biological product) or device product that has a primary completion date on or after September 27, 1997; or

(2) An applicable clinical trial that is subject to registration under § 11.22(a) and studies a drug product (including a biological product) or device product that is unapproved, unlicensed, or uncleared, regardless of whether approval, licensure, or clearance was, is, or will be sought, and that is not otherwise subject to results information submission in accordance with the regulation.

(c) Deadline for submission of clinical trial information:

(1) *General.* Except as provided in paragraphs (c)(2) and (c)(3) of this section, a responsible party for an applicable clinical trial that is subject to this section must submit the clinical trial registration information specified in § 11.28(a) and the clinical trial results information specified in § 11.48(a) not later than 30 calendar days after the submission date specified in the notification described in paragraph (a) of this section.

(2) *Exception.* If a responsible party submits a certification consistent with § 11.44(b) or (c) not later than 30 calendar days after the submission date specified in the notification described in paragraph (a) of this section, the responsible party must submit the clinical trial results information specified in § 11.48(a) not later than the deadline specified in § 11.44(b) or (c), as applicable.

(3) If a responsible party submitted clinical trial registration information describing the applicable clinical trial specified in the notification described in paragraph (a) of this section prior to the date on which the notification is sent to

the responsible party, the responsible party must update such clinical trial information to reflect changes, if any, in the applicable clinical trial not later than 30 calendar days after the submission date specified in the notification described in paragraph (a) of this section, irrespective of the deadline for updates specified in § 11.64.

§ 11.64 When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected?

(a) *Updates.* (1) Clinical trial registration information:

(i) The responsible party for an applicable clinical trial for which clinical trial registration information was required to be submitted if the clinical trial was initiated before January 18, 2017, must submit updates in accordance with the following:

(A) In general, changes to the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) that was required at the time of submission must be updated not less than once every 12 months.

(B) Overall Recruitment Status must be updated not later than 30 calendar days after any change in overall recruitment status.

(C) Primary Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual primary completion date.

(ii) The responsible party for an applicable clinical trial, or for another clinical trial for which registration information was voluntarily submitted pursuant to § 11.60(c), if the clinical trial was initiated on or after January 18, 2017, must submit updates in accordance with the following:

(A) In general, changes to clinical trial registration information specified in § 11.28 must be updated not less than once every 12 months.

(B) If the first human subject was not enrolled in the clinical trial at the time of registration, the Study Start Date data element must be updated not later than 30 calendar days after the first human subject is enrolled.

(C) Intervention Name(s) must be updated to a non-proprietary name not later than 30 calendar days after a non-proprietary name is established for any intervention included in the Intervention Name(s) data element.

(D) Availability of expanded access:

(*1*) If expanded access to an investigational drug product (including a biological product) becomes available after an applicable clinical trial of that product has been registered, the responsible party, if both the manufacturer of the investigational drug product (including a biological product) and the sponsor of the applicable clinical trial, must, not later than 30 calendar days after expanded access becomes available, update the Availability of Expanded Access data element for that applicable clinical trial and, unless an expanded access record has already been created as required by § 11.28(a)(2)(ii)(H), submit the data elements in accordance with § 11.28(c) to create an expanded access record.

(*2*) No later than 30 calendar days after the date on which the responsible party receives an NCT number for an expanded access record created as required by § 11.28(a)(2)(ii)(H), the responsible party must update the Availability of Expanded Access data element by entering the NCT number in the clinical trial record for the applicable clinical trial.

(E) Expanded access record:

(*1*) Expanded Access Status, under § 11.28(c)(2)(iv), must be updated not later than 30 calendar days after a change in the availability of expanded access to an investigational drug product (including a biological product) under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).

(*2*) Expanded Access Type, under § 11.28(c)(1)(x), must be updated not later than 30 calendar days after a change in the type(s) of expanded access available for an investigational drug product (including a biological product) under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).

(F) Overall Recruitment Status must be updated not later than 30 calendar days after any change in overall recruitment status. If, at any time, Overall Recruitment Status is changed to "suspended," "terminated," or "withdrawn," the responsible party must also submit the Why Study Stopped data element.

(G) Individual Site Status must be updated not later than 30 calendar days after a change in status for any individual site.

(H) Human Subjects Protection Review Board Status must be updated not later than 30 calendar days after a change in status.

(I) Primary Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual primary completion date. At the time, the date is changed to "actual," and the Enrollment data element specifying the actual number of participants enrolled must be submitted.

(J) Study Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual study completion date.

(K) Responsible Party, by Official Title must be updated not later than 30 calendar days after a change in the responsible party or the official title of the responsible party.

(L) Responsible Party Contact Information must be updated not later than 30 calendar days after a change in the responsible party or the contact information for the responsible party.

(M) Device Product Not Approved or Cleared by U.S. FDA must be updated not later than 15 calendar days after a change in approval or clearance status has occurred.

(N) Record Verification Date must be updated any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months, even if no other updated information is submitted at that time.

(O) If a protocol is amended in such a manner that changes are communicated to human subjects in the clinical trial, updates to any relevant clinical trial registration information data elements must be submitted not later than 30 calendar days after the protocol amendment is approved by a human subjects protection review board.

(iii) In addition to the update requirements established in paragraphs (a)(1)(i) and (a)(1)(ii) of this section, clinical trial registration information must be updated at the time that clinical trial results information for that clinical trial is initially submitted.

(A) If the clinical trial was initiated before January 18, 2017, a responsible party must submit updates to the clinical trial registration information described in § 11.64(a)(1)(i).

(B) If the clinical trial was initiated on or after January 18, 2017, the responsible party must submit updates to the clinical trial registration information in accordance with § 11.64(a)(1)(ii).

(2) *Clinical trial results information.* The responsible party for an applicable clinical trial, or for another clinical trial for which results information was voluntarily submitted pursuant to § 11.60(b) or (c), where the clinical trial has a Primary Completion Date on or after January 18, 2017, must submit updates in accordance with the following:

(i) In general, changes to required clinical trial results information, other than the protocol and statistical analysis plan specified in § 11.48(a)(5) and certain agreements specified in § 11.48(a)(6)(ii),must be updated not less than once every 12 months.

(ii) For applicable device clinical trials of unapproved or uncleared device products, the responsible party must update the following data elements, as defined in § 11.10(b), in accordance with the following:

(A) Intervention Name(s) must be updated to a non-proprietary name not later than 30 calendar days after a non-proprietary name is established for any intervention included in the Intervention Name(s) data element.

(B) Primary Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual primary completion date. At the time the date is changed to "actual," the Enrollment data element specifying the actual number of participants enrolled must be submitted.

(C) Study Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual study completion date.

(D) Overall Recruitment Status must be updated not later than 30 calendar days after any change in overall recruitment status. If, at any time, Overall Recruitment Status is changed to "suspended," "terminated," or "withdrawn," the responsible party must also submit the Why Study Stopped data element.

(E) Record Verification Date must be updated any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months, even if no other updated information is submitted at that time.

(3) A responsible party's obligation to submit updates as specified in this section ends on the date on which all required clinical trial results information has been submitted as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C)) and 42 U.S.C. 282(j)(3)(I)) or as specified in § 11.48, as applicable, and corrections have been made or addressed in response to any electronic notice received under § 11.64(b)(1). If no clinical trial results information is required to be submitted, a responsible party's obligation to submit updates to clinical trial registration information ends on the date on which all required clinical trial registration information has been submitted as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii) or § 11.28, as applicable, and corrections have been made or addressed in response to any electronic notice received under § 11.64(b)(1).

(4) *Public availability of updates.* (i) Updates to clinical trial registration information and clinical trial results information will be posted in accordance with § 11.35 and § 11.52, respectively.

(ii) The Director will retain prior clinical trial registration information and clinical trial results information and make it publicly available in accordance with § 11.35 and § 11.52, respectively, through *ClinicalTrials.gov* so that updates do not result in the removal of any information from the original submission or any preceding update.

(b) Corrections—(1) *Quality control.* After clinical trial registration information has been submitted as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) or § 11.28, as applicable, or clinical trial results information has been submitted as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)) or § 11.48, as applicable, including the updates specified in paragraph (a) of this section, the Director may provide electronic notification to the responsible party of apparent errors, deficiencies, and/or inconsistencies in the submitted information identified during procedures for quality control review established by the Director, as specified at *https://prsinfo.clinicaltrials.gov.* The responsible party must correct or address all apparent errors, deficiencies, and/or inconsistencies identified in the notification not later than 15 calendar days for clinical trial registration information, or 25 calendar days for clinical trial results information, after the date of the electronic notification sent to the responsible party.

(2) *Other corrections.* (i) A responsible party who becomes aware of errors, other than those specified in paragraph (b)(1) of this section, in any clinical trial information submitted under this part shall have not more than 15 calendar days for clinical trial registration information, or 25 calendar days for clinical trial results information, to correct or address such errors.

(ii) A responsible party's obligation to correct or address errors as specified in paragraph (b)(2) of this section ends on the date on which all required clinical trial results information has been submitted as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)) or § 11.48, as applicable, and corrections have been made or addressed in response to any electronic notice received under § 11.64(b)(1). If no clinical trial results information is required to be submitted, a responsible party's obligation to correct or address errors ends on the date on which all required clinical trial registration information has been submitted as specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) or § 11.28, as applicable, and corrections have been made or addressed in response to any electronic notice received under § 11.64(b)(1).

(3) Compliance with the quality control review process, including the requirements of this section, does not constitute a legal defense to enforcement pursuant to section 301(jj) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331(jj)), section 303(f)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 333(f)(3)), or any other Federal law.

Subpart E—Potential Legal Consequences of Non-compliance

§ 11.66 What are potential legal consequences of not complying with the requirements of this part?

(a) *Civil or criminal judicial actions.* Failure to comply with the requirements of this part, issued under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)), is a prohibited act under one or more provisions of section 301(jj) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(jj)):

(1) Failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service (42 U.S.C. 282(j)(5)(B)) that all applicable requirements of section 402(j) have been met, or knowingly submitting a false certification under section 402(j)(5)(B), is a prohibited act under section 301(jj)(1) of the Federal Food, Drug, and Cosmetic Act.

(2) Failure to submit clinical trial information required under section 402(j) of the Public Health Service Act is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act.

(3) Submission of clinical trial information under section 402(j) that is false or misleading in any particular is a prohibited act under section 301(jj)(3) of the Federal Food, Drug, and Cosmetic Act.

(b) *Civil monetary penalty actions.* Any person who violates section 301(jj) of the Federal Food, Drug, and Cosmetic Act is subject to civil monetary penalties under section 303(f)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(3)).

(c) *Grant funding actions.* Under section 402(j)(5)(A) of the Public Health Service Act (42 U.S.C. 282(j)(5)(A)), if an applicable clinical trial is funded in whole or part by the Department of Health and Human Services, any required grant or progress report forms must include a certification that the responsible party has made all required registration and results submissions. If it is not verified that the required registration and results clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted, any remaining funding for a grant or funding for a future grant to such grantee will not be released. If the head of an HHS agency verifies that a grantee has not submitted such required clinical trial information, the agency head will provide notice to the grantee of the non-compliance and allow the grantee 30 days to correct the non-compliance and submit the required clinical trial information.

Dated: September 8, 2016.

Francis S. Collins,

Director, National Institutes of Health.

Approved: Dated: September 9, 2016.

Sylvia Mathews Burwell,

Secretary.

[FR Doc. 2016–22129 Filed 9–16–16; 11:15 am]

BILLING CODE P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
1985

FEDERAL REGISTER

Vol. 81 Wednesday,
No. 183 September 21, 2016

Part III

The President

Proclamation 9496—Northeast Canyons and Seamounts Marine National Monument

Federal Register
Vol. 81, No. 183
Wednesday, September 21, 2016

Presidential Documents

Title 3—

The President

Proclamation 9496 of September 15, 2016

Northeast Canyons and Seamounts Marine National Monument

By the President of the United States of America

A Proclamation

For generations, communities and families have relied on the waters of the northwest Atlantic Ocean and have told of their wonders. Throughout New England, the maritime trades, and especially fishing, have supported a vibrant way of life, with deep cultural roots and a strong connection to the health of the ocean and the bounty it provides. Over the past several decades, the Nation has made great strides in its stewardship of the ocean, but the ocean faces new threats from varied uses, climate change, and related impacts. Through exploration, we continue to make new discoveries and improve our understanding of ocean ecosystems. In these waters, the Atlantic Ocean meets the continental shelf in a region of great abundance and diversity as well as stark geological relief. The waters are home to many species of deep-sea corals, fish, whales and other marine mammals. Three submarine canyons and, beyond them, four undersea mountains lie in the waters approximately 130 miles southeast of Cape Cod. This area (the canyon and seamount area) includes unique ecological resources that have long been the subject of scientific interest.

The canyon and seamount area, which will constitute the monument as set forth in this proclamation, is composed of two units, which showcase two distinct geological features that support vulnerable ecological communities. The Canyons Unit includes three underwater canyons—Oceanographer, Gilbert, and Lydonia—and covers approximately 941 square miles. The Seamounts Unit includes four seamounts—Bear, Mytilus, Physalia, and Retriever—and encompasses 3,972 square miles. The canyon and seamount area includes the waters and submerged lands within the coordinates included in the accompanying map. The canyon and seamount area contains objects of historic and scientific interest that are situated upon lands owned or controlled by the Federal Government. These objects are the canyons and seamounts themselves, and the natural resources and ecosystems in and around them.

The canyons start at the edge of the geological continental shelf and drop from 200 meters to thousands of meters deep. The seamounts are farther off shore, at the start of the New England Seamount chain, rising thousands of meters from the ocean floor. These canyons and seamounts are home to at least 54 species of deep-sea corals, which live at depths of at least 3,900 meters below the sea surface. The corals, together with other structure-forming fauna such as sponges and anemones, create a foundation for vibrant deep-sea ecosystems, providing food, spawning habitat, and shelter for an array of fish and invertebrate species. These habitats are extremely sensitive to disturbance from extractive activities.

Because of the steep slopes of the canyons and seamounts, oceanographic currents that encounter them create localized eddies and result in upwelling. Currents lift nutrients, like nitrates and phosphates, critical to the growth of phytoplankton from the deep to sunlit surface waters. These nutrients fuel an eruption of phytoplankton and zooplankton that form the base of the food chain. Aggregations of plankton draw large schools of small fish and then larger animals that prey on these fish, such as whales, sharks, tunas, and seabirds. Together the geology, currents, and productivity create diverse and vibrant ecosystems.

The Canyons

Canyons cut deep into the geological continental shelf and slope throughout the mid-Atlantic and New England regions. They are susceptible to active erosion and powerful ocean currents that transport sediments and organic carbon from the shelf through the canyons to the deep ocean floor. In Oceanographer, Gilbert, and Lydonia canyons, the hard canyon walls provide habitats for sponges, corals, and other invertebrates that filter food from the water to flourish, and for larger species including squid, octopus, skates, flounders, and crabs. Major oceanographic features, such as currents, temperature gradients, eddies, and fronts, occur on a large scale and influence the distribution patterns of such highly migratory oceanic species as tuna, billfish, and sharks. They provide feeding grounds for these and many other marine species.

Toothed whales, such as the endangered sperm whale, and many species of beaked whales are strongly attracted to the environments created by submarine canyons. Surveys of the area show significantly higher numbers of beaked whales present in canyon regions than in non-canyon shelf-edge regions. Endangered sperm whales, iconic in the region due to the historic importance of the species to New England's whaling communities, preferentially inhabit the U.S. Atlantic continental margin. Two additional species of endangered whales (fin whales and sei whales) have also been observed in the canyon and seamount area.

The Seamounts

The New England Seamount Chain was formed as the Earth's crust passed over a stationary hot spot that pushed magma up through the seafloor, and is now composed of more than 30 extinct undersea volcanoes, running like a curved spine from the southern side of Georges Bank to midway across the western Atlantic Ocean. Many of them have characteristic flat tops that were created by erosion by ocean waves and subsidence as the magma cooled. Four of these seamounts—Bear, Physalia, Retriever, and Mytilus—are in the United States Exclusive Economic Zone. Bear Seamount is approximately 100 million years old and the largest of the four; it rises approximately 2,500 meters from the seafloor to within 1,000 meters of the sea surface. Its summit is over 12 miles in diameter. The three smaller seamounts reach to within 2,000 meters of the surface. All four of these seamounts have steep and complex topography that interrupts existing currents, providing a constant supply of plankton and nutrients to the animals that inhabit their sides. They also cause upwelling of nutrient-rich waters toward the ocean surface.

Geographically isolated from the continental platform, these seamounts support highly diverse ecological communities with deep-sea corals that are hundreds or thousands of years old and a wide array of other benthic marine organisms not found on the surrounding deep-sea floor. They provide shelter from predators, increased food, nurseries, and spawning areas. The New England seamounts have many rare and endemic species, several of which are new to science and are not known to live anywhere else on Earth.

The Ecosystem

The submarine canyons and seamounts create dynamic currents and eddies that enhance biological productivity and provide feeding grounds for seabirds; pelagic species, including whales, dolphins, and turtles; and highly migratory fish, such as tunas, billfish, and sharks. More than ten species of shark, including great white sharks, are known to utilize the feeding grounds of the canyon and seamount area. Additionally, surveys of leatherback and loggerhead turtles in the area have revealed increased numbers above and immediately adjacent to the canyons and Bear Seamount.

Marine birds concentrate in upwelling areas near the canyons and seamounts. Several species of gulls, shearwaters, storm petrels, gannets, skuas, and terns, among others, are regularly observed in the region, sometimes in large aggregations. Recent analysis of geolocation data found that Maine's vulnerable Atlantic puffin frequents the canyon and seamount area between September and March, indicating a previously unknown wintering habitat for those birds.

These canyons and seamounts, and the ecosystem they compose, have long been of intense scientific interest. Scientists from government and academic oceanographic institutions have studied the canyons and seamounts using research vessels, submarines, and remotely operated underwater vehicles for important deep-sea expeditions that have yielded new information about living marine resources. Much remains to be discovered about these unique, isolated environments and their geological, ecological, and biological resources.

WHEREAS, the waters and submerged lands in and around the deep-sea canyons Oceanographer, Lydonia, and Gilbert, and the seamounts Bear, Physalia, Retriever, and Mytilus, contain objects of scientific and historic interest that are situated upon lands owned or controlled by the Federal Government;

WHEREAS, section 320301 of title 54, United States Code (the "Antiquities Act"), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Federal Government to be national monuments, and to reserve as a part thereof parcels of land, the limits of which shall be confined to the smallest area compatible with the proper care and management of the objects to be protected;

WHEREAS, it is in the public interest to preserve the marine environment, including the waters and submerged lands, in the area to be known as the Northeast Canyons and Seamounts Marine National Monument, for the care and management of the objects of historic and scientific interest therein;

WHEREAS, the well-being of the United States, the prosperity of its citizens and the protection of the ocean environment are complementary and reinforcing priorities; and the United States continues to act with due regard for the rights, freedoms, and lawful uses of the sea enjoyed by other nations under the law of the sea in managing the canyon and seamount area and does not compromise the readiness, training, and global mobility of the U.S. Armed Forces when establishing marine protected areas;

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by the authority vested in me by section 320301 of title 54, United States Code, hereby proclaim the objects identified above that are situated upon lands and interests in lands owned or controlled by the Federal Government to be the Northeast Canyons and Seamounts Marine National Monument (monument) and, for the purpose of protecting those objects, reserve as a part thereof all lands and interests in lands owned or controlled by the Federal Government within the boundaries described on the accompanying map entitled "Northeast Canyons and Seamounts Marine National Monument," which is attached hereto, and forms a part of this proclamation. The Federal lands and interests in lands reserved consist of approximately 4,913 square miles, which is the smallest area compatible with the proper care and management of the objects to be protected.

The establishment of the monument is subject to valid existing rights. All Federal lands and interests in lands within the boundaries of the monument are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, leasing, or other disposition under the public land laws to the extent that those laws apply, including but not limited to, withdrawal from location, entry and patent under mining laws, and from disposition under all laws relating to development of oil and gas, minerals, geothermal, or renewable energy. Lands and interest in lands within the monument not owned or controlled by the United States shall be reserved as part of the monument upon acquisition of title or control by the United States.

Management of the Marine National Monument

The Secretaries of Commerce and the Interior (Secretaries) shall share management responsibility for the monument. The Secretary of Commerce, through the National Oceanic and Atmospheric Administration (NOAA), and in consultation with the Secretary of the Interior, shall have responsibility for management of activities and species within the monument under the Magnuson-Stevens Fishery Conservation and Management Act, the Endangered Species Act (for species regulated by NOAA), the Marine Mammal Protection Act, and any other applicable Department of Commerce legal authorities. The Secretary of the Interior, through the United States Fish and Wildlife Service (FWS), and in consultation with the Secretary of Commerce, shall have responsibility for management of activities and species within the monument under its applicable legal authorities, including the National Wildlife Refuge System Administration Act, the Refuge Recreation Act, and the Endangered Species Act (for species regulated by FWS), and Public Law 98–532 and Executive Order 6166 of June 10, 1933.

The Secretaries shall prepare a joint management plan, within their respective authorities, for the monument within 3 years of the date of this proclamation, and shall promulgate as appropriate implementing regulations, within their respective authorities, that address any further specific actions necessary for the proper care and management of the objects and area identified in this proclamation. The Secretaries shall revise and update the management plan as necessary. In developing and implementing any management plans and any management rules and regulations, the Secretaries shall consult, designate, and involve as cooperating agencies the agencies with jurisdiction or special expertise, including the Department of Defense and Department of State, in accordance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations. In addition, the Secretaries shall work to continue advances in resource protection in the Monument area that have resulted from a strong culture of collaboration and enhanced stewardship of marine resources.

This proclamation shall be applied in accordance with international law, and the Secretaries shall coordinate with the Department of State to that end. The management plans and their implementing regulations shall not unlawfully restrict navigation and overflight and other internationally recognized lawful uses of the sea in the monument and shall incorporate the provisions of this proclamation regarding U.S. Armed Forces actions and compliance with international law. No restrictions shall apply to or be enforced against a person who is not a citizen, national, or resident alien of the United States (including foreign flag vessels) unless in accordance with international law. Also, in accordance with international law, no restrictions shall apply to foreign warships, naval auxiliaries, and other vessels owned or operated by a state and used, for the time being, only on government non-commercial service, in order to fully respect the sovereign immunity of such vessels under international law.

Restrictions

Prohibited Activities

The Secretaries shall prohibit, to the extent consistent with international law, any person from conducting or causing to be conducted the following activities:

1. Exploring for, developing, or producing oil and gas or minerals, or undertaking any other energy exploration or development activities within the monument.

2. Using or attempting to use poisons, electrical charges, or explosives in the collection or harvest of a monument resource.

3. Introducing or otherwise releasing an introduced species from within or into the monument.

4. Removing, moving, taking, harvesting, possessing, injuring, disturbing, or damaging, or attempting to remove, move, take, harvest, possess, injure, disturb, or damage, any living or nonliving monument resource, except as provided under regulated activities below.

5. Drilling into, anchoring, dredging, or otherwise altering the submerged lands; or constructing, placing, or abandoning any structure, material, or other matter on the submerged lands, except for scientific instruments and constructing or maintaining submarine cables.

6. Fishing commercially or possessing commercial fishing gear except when stowed and not available for immediate use during passage without interruption through the monument, except for the red crab fishery and the American lobster fishery as regulated below.

Regulated Activities

Subject to such terms and conditions as the Secretaries deem appropriate, the Secretaries, pursuant to their respective authorities, to the extent consistent with international law, may permit any of the following activities regulated by this proclamation if such activity is consistent with the care and management of the objects within the monument and is not prohibited as specified above:

1. Research and scientific exploration designed to further understanding of monument resources and qualities or knowledge of the North Atlantic Ocean ecosystem and resources.

2. Activities that will further the educational value of the monument or will assist in the conservation and management of the monument.

3. Anchoring scientific instruments.

4. Recreational fishing in accordance with applicable fishery management plans and other applicable laws and other requirements.

5. Commercial fishing for red crab and American lobster for a period of not more than 7 years from the date of this proclamation, in accordance with applicable fishery management plans and other regulations, and under permits in effect on the date of this proclamation. After 7 years, red crab and American lobster commercial fishing is prohibited in the monument.

6. Other activities that do not impact monument resources, such as sailing or bird and marine mammal watching so long as those activities are conducted in accordance with applicable laws and regulations, including the Marine Mammal Protection Act. Nothing in this proclamation is intended to require that the Secretaries issue individual permits in order to allow such activities.

7. Construction and maintenance of submarine cables.

Regulation of Scientific Exploration and Research

The prohibitions required by this proclamation shall not restrict scientific exploration or research activities by or for the Secretaries, and nothing in this proclamation shall be construed to require a permit or other authorization from the other Secretary for their respective scientific activities.

Emergencies and Law Enforcement Activities

The prohibitions required by this proclamation shall not apply to activities necessary to respond to emergencies threatening life, property, or the environment, or to activities necessary for law enforcement purposes.

U.S. Armed Forces

1. The prohibitions required by this proclamation shall not apply to activities and exercises of the U.S. Armed Forces, including those carried out by the United States Coast Guard.

2. The U.S. Armed Forces shall ensure, by the adoption of appropriate measures not impairing operations or operation capabilities, that its vessels and aircraft act in a manner consistent so far as is practicable, with this proclamation.

3. In the event of threatened or actual destruction of, loss of, or injury to a monument resource or quality resulting from an incident, including but not limited to spills and groundings, caused by a component of the Department of Defense or the United States Coast Guard, the cognizant component shall promptly coordinate with the Secretaries for the purpose of taking appropriate action to respond to and mitigate any harm and, if possible, restore or replace the monument resource or quality.

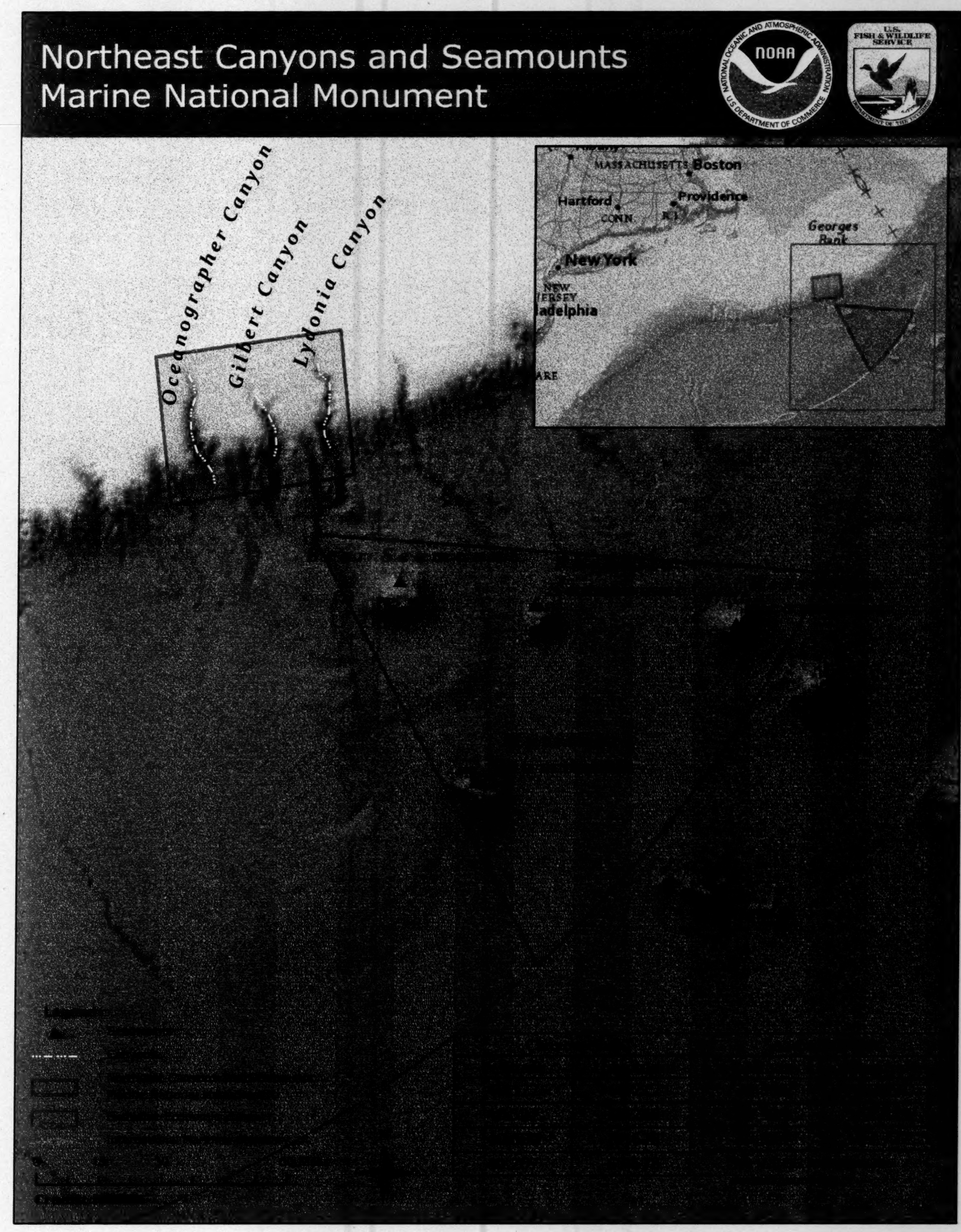
4. Nothing in this proclamation or any regulation implementing it shall limit or otherwise affect the U.S. Armed Forces' discretion to use, maintain, improve, manage or control any property under the administrative control of a Military Department or otherwise limit the availability of such property for military mission purposes, including, but not limited to, defensive areas and airspace reservations.

Other Provisions

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the monument shall be the dominant reservation.

Warning is hereby given to all unauthorized persons not to appropriate, excavate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.


Northeast Canyons and Seamounts
Marine National Monument
NOAA
U.S. Fish & Wildlife Service
Oceanographer Canyon
Gilbert Canyon
Lydonia Canyon
MASSACHUSETTS
Boston
Hartford
CONN.
Providence
R.I.
Georges Bank
New York
NEW JERSEY
adelphia
ARE

[FR Doc. 2016–22921
Filed 9–20–16; 11:15 am]
Billing code 3510–07–C

Reader Aids

Federal Register

Vol. 81, No. 183

Wednesday, September 21, 2016

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and Code of Federal Regulations are located at: **www.ofr.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, SEPTEMBER

60235–60580	1
60581–61098	2
61099–61582	6
61583–61972	7
61973–62352	8
62353–62602	9
62603–62808	12
62809–63050	13
63051–63360	14
63361–63670	15
63671–64048	16
64049–64344	19
64345–64758	20
64759–65168	21

CFR PARTS AFFECTED DURING SEPTEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

2 CFR

2800	61981

3 CFR

Proclamations:

9479	61973
9480	61975
9481	61977
9482	61979
9483	62347
9484	62349
9485	62351
9486	62599
9487	63351
9488	63353
9489	63355
9490	63357
9491	63359
9492	63671
9493	64049
*	
9495	64757
9496	65161

Executive Orders:

13396 (revoked by 13739)	63673
13739	63673

Administrative Orders:

Notices:	
Notice of August 30, 2016	60579
Notice of September 15, 2016	64343
Presidential Determinations:	
No. 2016–10 of September 12, 2016	64749
No. 2016–11 of September 13, 2016	64047

5 CFR

870	60235
2417	63361
2640	61099

Proposed Rules:

1800	60649
9801	61628

6 CFR

27	62353

Proposed Rules:

5	60297

7 CFR

56	63675
930	63676
983	63679
987	64759
1150	62809
1499	62603
1599	62614
1780	63051

Proposed Rules:

923	64785
981	62668
984	63718, 63721
989	63723
999	63723

8 CFR

214	60581
236	62353
238	62353
239	62353
240	62353
241	62353
270	62353
274a	62353
280	62353
287	62353

10 CFR

171	61100
430	61982

Proposed Rules:

429	60784, 64580
430	60784
431	62980, 64580

12 CFR

217	63682
602	63365

Proposed Rules:

7	63428
51	62835
1231	64357

13 CFR

123	63366

Proposed Rules:

107	64075
311	64787
312	64805

14 CFR

25	60236, 60240, 60241, 63051
39	60243, 60246, 60248, 60252, 60582, 61102, 61983, 61985, 61987, 61990, 61993, 61996, 61999, 63367, 63370, 63374, 63688, 63691, 64051, 64053, 64057
61	61583
71	62002, 62003, 62807, 62810
91	61583
93	62802, 62811
135	61583

Proposed Rules:

25	64360
39	62022, 62024, 62026,

62029, 62031, 62035, 62037, 62668, 62672, 62676, 62679, 62845, 63433, 63725, 64080, 64083
71 ....62040, 62041, 62044
73 62847
193 64085
382 61145

15 CFR

730 ....60254, 64656
732 60254
734 ....60254, 64656
736 60254
738 ....60254, 64656
740 ....60254, 64656
742 ....60254, 64656
743 ....60254, 64656
744 ....61595, 64694
746 60254
747 60254
748 ....60254, 61104, 64656
750 60254
754 60254
756 60254
758 60254
760 60254
762 60254
764 60254
766 60254
768 60254
770 ....60254, 64656
772 ....60254, 64656
774 ....60254, 64656

16 CFR

305 63634
701 63664
702 63664
803 60257

Proposed Rules:

Ch. II 60298
305 62681
314 61632
682 63435
1500 61146

17 CFR

37 64272
38 64272
39 64312
49 64272
Ch. I 63376
240 60585
275 60418
279 60418

Proposed Rules:

4 61147
Ch. II 64364
229 62689
232 62689
239 62689
249 62689
275 ....60651, 60653

18 CFR

Proposed Rules:

806 64812
808 64812

19 CFR

165 62004

Proposed Rules:

111 63049

20 CFR

404 64060
416 64060

Proposed Rules:

404 62560
416 62560

21 CFR

17 62358
20 62004
25 62004
117 64060
170 62004
184 62004
186 62004
310 61106
507 64060
558 63053
570 62004
878 64761
1308 61130

Proposed Rules:

15 60299
73 63728
1300 63576
1301 63576
1302 63576
1303 63576
1304 63576
1308 ....61636, 63576
1309 63576
1310 63576
1312 63576
1313 63576
1314 63576
1315 63576
1316 63576
1321 63576

22 CFR

42 63694
51 60608
120 62004
125 62004
126 62004
130 62004

Proposed Rules:

22 64088
96 62322

23 CFR

Proposed Rules:

Ch. 1 63153

24 CFR

5 64763
100 63054

Proposed Rules:

35 60304

26 CFR

1 ....60609, 62359, 64061
20 60609
25 60609
26 60609
31 60609
301 60609

Proposed Rules:

1 63154
301 63154

27 CFR

9 62626

Proposed Rules:

4 62046
9 ....62047, 64368
24 62046

28 CFR

66 61981
70 61981
104 60617

Proposed Rules:

0 63155
16 64092
44 63155

29 CFR

1910 60272
1915 60272
1926 60272
1986 63396
4022 63414
4044 63414

Proposed Rules:

1915 62052
4000 64700
4001 64700
4003 64700
4041 64700
4041A 64700
4050 64700

30 CFR

250 61834
800 61612

32 CFR

66 64061
199 ....61068, 63695
252 61615
269 62629
706 62008
1909 64063
2002 63324

Proposed Rules:

50 60655

33 CFR

27 62353
100 ....62365, 63075, 63695, 63697, 63698, 64345
117 ....60620, 60621, 61615, 62366, 62367, 62368, 63700, 64347
165 ....61133, 61616, 62010, 62368, 62371, 63075, 63098, 63416, 63418, 64266, 64268

Proposed Rules:

100 ....61148, 63437
110 61639
165 ....60663, 63728

34 CFR

Ch. I 63099
222 64728
Ch. III 62631

Proposed Rules:

200 61148

37 CFR

202 62373
387 62812

Proposed Rules:

201 63440
204 63440

38 CFR

17 62631

Proposed Rules:

3 62419

39 CFR

Proposed Rules:

501 61159
3015 63445
3060 63445

40 CFR

52 ....60274, 62373, 62375, 62378, 62381, 62387, 62390, 62813, 63102, 63104, 63106, 63107, 63701, 63704, 63705, 64070, 64072, 64347, 64349, 64350, 64354
55 62393
63 63112
70 62387
81 ....61136, 62390
127 62395
180 ....60621, 61617, 63131, 63707, 63710
228 61619
300 62397

Proposed Rules:

52 ....60329, 62066, 62426, 62849, 63156, 63448, 63732, 63734, 64372, 64377
55 62427
70 62426
97 63156
131 63158
300 62428

41 CFR

102–74 63134
Ch. 109 63262
301–11 63134
301–51 63137
301–70 (2 documents) 63134, 63137

42 CFR

3 61538
8 62403
11 64982
73 63138
102 62817
402 61538
403 ....61538, 63860
411 61538
412 61538
416 63860
418 63860
422 61538
423 61538
441 63860
460 ....61538, 63860
482 63860
483 ....61538, 63860
484 63860
485 63860
486 63860
488 61538
491 63860
493 61538
494 63860
1003 61538

Proposed Rules:

59 61639
88 60329
455 64383
1007 64383

43 CFR

10 64356

Proposed Rules:

2 64401

44 CFR

Proposed Rules:

9....64403

45 CFR

79....61538
93....61538
102....61538
147....61538
150....61538
155....61538
156....61538
158....61538
160....61538
303....61538
Ch. XIII....61294

Proposed Rules:

144....61456
146....61456
147....61456
148....61456
153....61456
154....61456
155....61456
156....61456
157....61456
158....61456

46 CFR

106....63420

47 CFR

20....60625
51....62632
63....62632
64....62818
73....62657
90....63714

Proposed Rules:

73....62433
90....64825

48 CFR

1816....63143
1832....63143
1842....63143
1852....63143

Proposed Rules:

49....63158
212....61646
227....61646
252....61646
501....62434
511....62434
515....62445
517....62434
532....62434
536....62434
538....62445
543....62434
546....62434
552....62434, 62445

49 CFR

Appendix G to Subchapter B of Ch. III....60633
393....60633
661....60278
1503....62353

Proposed Rules:

107....61742
171....61742
172....61742
173....61742
175....61742
176....61742
178....61742
180....61742
391....62448
393....61942
541....64405
571....61942
577....60332
Ch. X....61647

50 CFR

17....62657, 62826
20....62404
216....62010, 62018
223....62018, 62260
224....62018, 62260
622....60285
635....60286
648....60635, 60636
660....60288
665....61625, 63145, 64356
679....60295, 60648, 61142, 61143, 62659, 62833, 63716, 64782, 64784

Proposed Rules:

17....61658, 62450, 62455, 63160, 63454, 64414, 64829, 64843, 64857
217....61160
223....64094, 64110
224....64110
622....62069
648....60666, 64426
660....61161
680....62850

* **Editorial Note:** Proclamation number 9494 will not be used because a proclamation numbered 9494 appeared on the Public Inspection List on Friday September 16, 2016, but was withdrawn by the issuing agency before publication in the **Federal Register**.

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List August 4, 2016

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.